PHARMACEUTICAL EVERGREENING, ACCESS TO MEDICINES AND PATENT LAW: RE-EXAMINING THE INDIAN MODEL IN A POST-TRIPS WORLD

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ABSTRACT

The pharmaceutical patent system sits at the intersection of two competing imperatives, incentivising innovation and ensuring affordable access to medicines. While the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) globalised minimum standards of patent protection, it also intensified concerns regarding "evergreening" a strategic practice whereby pharmaceutical patentees extend market exclusivity through secondary and incremental patents. India responded to this challenge through a consciously public-health-oriented patent regime, most notably through Section 3(d) of the Patents Act, 1970, which restricts the patentability of new forms of known substances absent demonstrable therapeutic efficacy. This paper undertakes a comprehensive doctrinal, constitutional, and policy analysis of the Indian anti-evergreening framework in the post-TRIPS era. It critically examines the jurisprudence of the Supreme Court and High Courts, particularly the Novartis decision and its progeny, and evaluates whether the Indian model has succeeded in preserving access to medicines without undermining genuine pharmaceutical innovation. The paper further situates India's approach within a comparative international context, analysing the regulatory and judicial treatment of secondary patents in the United States and the European Union. It argues that while the Indian framework represents a globally significant experiment in balancing patent monopoly and public health, emerging trade pressures, incremental innovation strategies, and regulatory capture threaten to dilute its normative foundations. The paper concludes by proposing a principled recalibration of patentability standards, evidentiary thresholds, and institutional scrutiny mechanisms to preserve India's constitutional commitment to health while remaining compliant with its international obligations.

Keywords: Pharmaceutical Patents, Evergreening, Section 3(d), Access to Medicines, TRIPS, Public Health, Incremental Innovation, Novartis Case, Patent Policy.

1. Introduction

Few areas of intellectual property law expose the moral, constitutional, and political tensions of the patent system as starkly as pharmaceutical patents. Unlike most other patentable subject matter, medicines are not merely commercial goods. They are essential instruments for the preservation of life, health, and human dignity. The legal regime governing their production, pricing, and distribution therefore operates not in a morally neutral market, but in a domain where monopoly rights granted by the State can directly determine who lives, who suffers, and who dies. This places pharmaceutical patent law in a unique normative position, where classical theories of innovation incentives collide with constitutional commitments to public health and social justice.[1]

At the heart of the modern patent system lies a fundamental duality. On the one hand, patent law is justified as a mechanism to encourage costly and uncertain research and development by granting inventors temporary market exclusivity.[2] On the other hand, this very exclusivity necessarily restricts competition, elevates prices, and limits access effects that are particularly severe in the pharmaceutical sector, where demand is inelastic and substitutes are often unavailable.[3] Patent law thus does not merely regulate markets; it structures access to essential goods. In developing countries, this tension is not an abstract policy dilemma but a concrete governance problem, as large sections of the population depend on affordable generics for basic healthcare.[4]

This structural conflict became globally entrenched after the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which universalised minimum standards of pharmaceutical patent protection and compelled countries like India to dismantle their earlier, public-health-oriented patent regimes.[5] Prior to TRIPS, India's exclusion of product patents in medicines enabled the growth of a robust generic industry and positioned

[1] See U.N. Comm. on Econ., Soc. & Cultural Rts., General Comment No. 14: The Right to the Highest Attainable Standard of Health, ¶ 12, U.N. Doc. E/C.12/2000/4 (2000).
[2] WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 294–95 (2003).
[3] Aidan Hollis & Thomas Pogge, The Health Impact Fund: Making New Medicines Accessible for All, 375 LANCET 166, 166–69 (2010).
[4] Sudip Chaudhuri, The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries 3–7 (2005).
[5] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27–34, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

the country as a central supplier of affordable drugs to the developing world.[6] The post-TRIPS transition, however, fundamentally altered the legal landscape by reintroducing pharmaceutical product patents and, with them, the risk of monopolistic pricing and strategic market foreclosure.

It is within this transformed global patent order that the phenomenon of "evergreening" has acquired critical significance. Evergreening refers not to a single abusive practice but to a sophisticated portfolio of legal and regulatory strategies through which pharmaceutical companies seek to extend effective market exclusivity beyond the original patent term by obtaining secondary patents over minor modifications of existing drugs—such as new forms, new dosages, new combinations, or new methods of use.[7] While such incremental innovations may sometimes reflect genuine therapeutic improvements, in many cases they function primarily as tools of life-cycle management designed to delay generic entry and preserve monopoly rents.[8] The problem of evergreening is therefore not incidental; it is a structural by-product of the interaction between strong patent regimes, regulatory exclusivities, and the commercial imperatives of the modern pharmaceutical industry.

What makes the pharmaceutical context normatively distinct is that these strategies do not merely affect market efficiency they directly shape the accessibility and affordability of life-saving medicines. The extension of exclusivity by even a few years can impose enormous social costs, measured in both fiscal burdens on public health systems and in human suffering caused by untreated or inadequately treated disease.[9] This is why evergreening has increasingly been framed not only as a competition or patent quality issue, but as a question of distributive justice and constitutional governance.

India's response to this challenge has been globally distinctive. Through the introduction of Section 3(d) into the Patents Act in 2005, the Indian legislature sought to draw a principled line between genuine pharmaceutical innovation and strategic evergreening by denying patent protection to new forms of known substances unless they demonstrate enhanced therapeutic efficacy. This provision, upheld and elaborated by the Supreme Court in *Novartis AG v. Union*

[6] Janice M. Mueller, The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation, 68 U. PITT. L. REV. 491, 497–503 (2007).
[7] C. Scott Hemphill & Bhaven N. Sampat, Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals, 31 J. HEALTH ECON. 327, 328–30 (2012).
[8] Robin Feldman, May Your Drug Price Be Evergreen, 5 J.L. & BIOSCI. 590, 593–96 (2018).
[9] Brook K. Baker, Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage, 34 AM. J.L. & MED. 303, 306–09 (2008).

of India, represents one of the most explicit attempts by any jurisdiction to embed public health considerations directly into the threshold of patentability itself.[10] In doing so, Indian patent law departed from the dominant trend of treating access concerns as external correctives to patent rights (through compulsory licensing or price control) and instead internalised them within the core architecture of patent doctrine.

This legislative and judicial experiment has placed India at the centre of a global debate on the proper balance between innovation incentives and access to medicines. While hailed by public health advocates as a model for the Global South, it has simultaneously attracted sustained criticism from segments of the pharmaceutical industry and from countries advocating stronger forms of intellectual property protection.[11]

Against this backdrop, the paper asks four interrelated questions. First, how has the globalisation of pharmaceutical patent standards under TRIPS reshaped the structural conditions for evergreening? Second, does Section 3(d) and the Indian jurisprudence built around it succeed in drawing a coherent and principled distinction between genuine innovation and rent-seeking? Third, how does the Indian approach compare with the regulatory and judicial treatment of secondary patents in the United States and the European Union? And finally, is the Indian model normatively sustainable in the face of contemporary trade pressures and evolving innovation strategies?

Methodologically, the paper adopts a doctrinal and comparative approach, grounded in close analysis of statutory texts, judicial decisions, and international legal instruments, while situating them within their broader economic and constitutional context. It does not attempt an empirical measurement of drug prices or innovation outputs; rather, it interrogates the legal architecture that structures these outcomes. The scope of the analysis is deliberately focused on pharmaceutical patents, not because other fields of intellectual property are normatively unimportant, but because nowhere else does the tension between monopoly and human welfare appear in such an acute and morally transparent form.

In this sense, the Indian experiment with anti-evergreening is not merely a technical feature of patent law. It is a test case for a deeper proposition: whether a developing constitutional

[10] Novartis AG v. Union of India, (2013) 6 SCC 1.
[11] Frederick M. Abbott & Jerome H. Reichman, The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions, 10 J. INT'L ECON. L. 921, 923–26 (2007).

democracy can meaningfully discipline global monopoly capitalism in sectors that directly implicate the right to life and health.

2. TRIPS and the Globalisation of Pharmaceutical Patent Standards

The contemporary structure of pharmaceutical patent law in India cannot be understood without situating it within the profound transformation brought about by the Agreement on Trade-Related Aspects of Intellectual Property Rights. TRIPS did not merely harmonise technical standards of patent protection. It fundamentally reconfigured the relationship between intellectual property, trade, and development by relocating questions of innovation policy from the domain of national legislative choice to the architecture of global economic governance. In the pharmaceutical sector, this shift proved especially consequential because it dismantled alternative development models that many countries, including India, had consciously adopted in order to secure affordable access to medicines.

2.1 India's Pre-TRIPS Patent Regime and the Rejection of Product Patents

For much of the post-independence period, India pursued a deliberately non-proprietary approach to pharmaceutical innovation. The Patents Act of 1970 excluded product patents for food and medicines and permitted only process patents of limited duration. This legislative design was not accidental or technologically backward. It reflected a carefully considered policy choice informed by the recommendations of expert committees which had concluded that strong product patent protection in medicines would entrench foreign monopolies and render essential drugs unaffordable for the vast majority of the population.[12] The result was the emergence of a highly competitive domestic pharmaceutical industry that specialised in reverse engineering and low-cost manufacturing. By the 1990s, India had become one of the largest suppliers of generic medicines in the developing world and an indispensable actor in global public health supply chains.[13]

This regime demonstrated that pharmaceutical production and technological capability could flourish even in the absence of product patent monopolies. Innovation in manufacturing processes, scale efficiencies, and formulation techniques became the backbone of the industry.

[12] Government of India, Report of the Committee on the Revision of the Patent Law (Rajagopala Ayyangar Committee Report) 21–28 (1959).
[13] Sudip Chaudhuri, The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS and Developing Countries 40–52 (2005).

At the same time, drug prices remained among the lowest in the world.[14]In retrospect, the pre-TRIPS Indian model represented a radically different understanding of the social function of patent law, one in which the primary objective was not to maximise returns to originator firms but to ensure the widest possible diffusion of essential technologies.

2.2 TRIPS Obligations and the Reintroduction of Pharmaceutical Product Patents

This policy autonomy was decisively curtailed with India's accession to the World Trade Organization and its acceptance of the TRIPS Agreement. TRIPS required all member states to provide patent protection in all fields of technology, including pharmaceuticals, subject to limited and narrowly framed exceptions.[15] Although developing countries were granted a transitional period, the direction of legal change was clear and irreversible. India was compelled to amend its patent law to allow pharmaceutical product patents with a term of twenty years, thereby dismantling the core architecture of its earlier regime.[16]

At the same time, TRIPS was presented not merely as a harmonisation instrument but as a framework that allegedly balanced private rights with public interest. It incorporated certain flexibilities, including compulsory licensing, parallel importation, and limited exceptions to patent rights.[17] In formal terms, therefore, the Agreement did not mandate an unqualified or absolutist model of patent protection. In practice, however, the combination of political pressure, trade retaliation threats, and interpretive uncertainty meant that many developing countries remained reluctant to use these safeguards in any meaningful way.[18]

India's legislative response to TRIPS was thus marked by a dual strategy. On the surface, it complied with the minimum international standards by reintroducing product patents. At a deeper level, it attempted to preserve policy space through carefully designed internal limits on patentability, most notably through the introduction of Section 3(d). This move reflected a recognition that once strong patent rights are granted, it becomes institutionally and politically

[14] Janice M. Mueller, The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation, 68 U. PITT. L. REV. 491, 498–503 (2007).
[15] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[16] The Patents (Amendment) Act, 2005, No. 15 of 2005, India.
[17] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 30–31, Apr. 15, 1994, 1869 U.N.T.S. 299.
[18] Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 AM. J. INT'L L. 317, 320–24 (2005).

far more difficult to correct their social consequences through ex post mechanisms alone.

2.3 The Political Economy of TRIPS and the North–South Divide

The globalisation of pharmaceutical patent standards under TRIPS was not the outcome of a neutral or technocratic process. It was the result of sustained lobbying by multinational pharmaceutical corporations and the governments of developed countries, particularly the United States and members of the European Union, which sought to export their domestic standards of intellectual property protection to the rest of the world.[19] For these actors, TRIPS was less about promoting innovation in the abstract and more about securing international legal guarantees for the protection of knowledge assets in global markets.

From the perspective of developing countries, however, this harmonisation project entailed a significant redistribution of economic rents and regulatory authority. It required countries with radically different levels of income, disease burdens, and technological capacity to operate under a uniform patent regime designed around the interests and cost structures of advanced economies.[20] The resulting asymmetry explains why TRIPS has often been described not as a development-neutral agreement but as a constitutional document of the global knowledge economy that entrenches existing hierarchies of production and ownership.

In the pharmaceutical sector, this structural imbalance has especially severe consequences. The costs of research and development are concentrated in a handful of countries and firms, while the burden of disease is disproportionately borne by populations in the Global South. A uniform global patent regime therefore tends to socialise the costs of monopoly pricing while privatising the benefits of innovation.[21] It is against this backdrop that resistance to evergreening and secondary patenting strategies in countries like India must be understood not as protectionism or hostility to innovation but as an attempt to correct a deeper distributive distortion embedded in the global patent order.

2.4 Public Health Safeguards and the Doha Recalibration

The tensions inherent in TRIPS became politically unavoidable in the late 1990s and early

[19] Peter Drahos & John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? 119–45 (2002).
[20] Carlos M. Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options 5–12 (2000).
[21] Brook K. Baker, Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent Registration Linkage, 34 AM. J.L. & MED. 303, 307–10 (2008).

2000s, particularly in the context of the HIV/AIDS crisis, when patent-protected drug prices placed life-saving treatments beyond the reach of millions in developing countries. This crisis culminated in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001, which affirmed that TRIPS should be interpreted and implemented in a manner supportive of public health and the promotion of access to medicines for all.[22]

The Doha Declaration clarified the right of member states to use compulsory licensing and other TRIPS flexibilities and rejected the notion that intellectual property protection is an end in itself. It marked an important symbolic and legal recognition that patent law operates within a broader framework of human welfare and social policy. At the same time, the subsequent history of pharmaceutical patent disputes shows that the practical space for using these safeguards remains politically contested and institutionally constrained.[23]

In this sense, India's strategy of embedding access considerations directly into the criteria of patentability itself represents a more structurally robust response to the public health challenge than reliance on post-grant corrective mechanisms alone. Rather than treating access as an exception to monopoly, the Indian model attempts to prevent unjustified monopolies from arising in the first place. This design choice situates India's patent regime not at the margins of TRIPS, but at the centre of the unresolved normative conflict within the global intellectual property system itself.

3. Evergreening as a Legal and Economic Strategy

The concept of evergreening occupies an uneasy and contested space within pharmaceutical patent law. It is not a term of art found in statutes or treaties, nor does it refer to a single uniform legal technique. Rather, it describes a strategic pattern of behaviour through which originator pharmaceutical firms seek to extend their effective market exclusivity beyond the life of the original patent by constructing layered portfolios of secondary patents around a single therapeutic product. This strategy operates at the intersection of patent doctrine, regulatory law, and market structure, and it has become one of the most consequential mechanisms through

[22] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001).
[23] Ellen 't Hoen, The Global Politics of Pharmaceutical Monopoly Power 87–112 (2009).

which monopoly power is preserved in the modern pharmaceutical economy.[24]

3.1 Conceptualising Evergreening

Evergreening is often described in polemical terms as an abuse of the patent system. While this description captures its social effects, it risks obscuring a more uncomfortable truth. Many evergreening practices operate within the formal boundaries of patent law as it exists in several jurisdictions. They are not necessarily illegal. They are the predictable outcome of a legal regime that rewards the accumulation and strategic deployment of exclusionary rights without sufficiently rigorous scrutiny of inventive merit.[25] From this perspective, evergreening is less a pathological deviation and more a rational response to the incentive structures embedded in contemporary patent systems.

The modern pharmaceutical market is characterised by extraordinarily high development costs, regulatory uncertainty, and a steep drop in revenues once generic competition enters. In such an environment, firms are under constant pressure to extend the commercial life of their most profitable products. Secondary patenting strategies offer a legally sanctioned method of doing so by transforming what is, in substance, a single therapeutic breakthrough into a dense thicket of overlapping legal rights.[26] The effect is not merely to protect innovation but to reshape the competitive landscape in ways that raise entry barriers and increase litigation risks for generic manufacturers.

3.2 Techniques of Evergreening and the Architecture of Secondary Patents

The legal techniques used in evergreening are diverse but structurally similar. They typically involve claiming patent protection over incremental or peripheral aspects of an existing drug rather than over a new therapeutic principle. Common examples include patents over new crystalline forms, salts, esters, or polymorphs of known substances, patents over new dosage regimes or methods of administration, patents over fixed-dose combinations, and patents over new therapeutic uses of known compounds.[27]

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[24] C. Scott Hemphill & Bhaven N. Sampat, Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals, 31 J. HEALTH ECON. 327, 328–30 (2012).
[25] Robin Feldman, May Your Drug Price Be Evergreen, 5 J.L. & BIOSCI. 590, 593–96 (2018).
[26] Michael A. Carrier & Steve D. Shadowen, Product Hopping: A New Framework, 92 NOTRE DAME L. REV. 167, 170–74 (2016).
[27] Carlos M. Correa, Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, 12 S. J. TECH. & TRADE 1, 8–12 (2011).

Individually, some of these modifications may represent genuine technical improvements. Collectively, however, they often function as part of a coordinated life-cycle management strategy. The goal is not simply to obtain additional patents but to create a legal environment in which the expiry of the primary compound patent does not translate into meaningful market competition.[28] Even when secondary patents are ultimately invalidated, their mere existence can delay generic entry through litigation, regulatory uncertainty, and commercial risk.

This phenomenon is sometimes described as the creation of "patent thickets", dense webs of overlapping rights that make it economically and legally hazardous for competitors to operate.[29] In the pharmaceutical context, these thickets are particularly potent because market entry is already conditioned by regulatory approval processes, data exclusivity regimes, and complex supply chains. Patent layering thus amplifies existing structural barriers and converts formal legal rights into durable market power.

3.3 Economic Consequences for Competition and Access

The economic effects of evergreening extend far beyond the abstract domain of patent doctrine. By delaying or fragmenting generic entry, secondary patent strategies preserve high prices long after the original research and development costs have been recouped. This has direct consequences for public health budgets, insurance systems, and individual patients, especially in low- and middle-income countries where out-of-pocket expenditure remains a dominant mode of healthcare financing.

Empirical studies have shown that the entry of generic competition typically leads to dramatic price reductions, often in the range of 80 to 90 per cent.[30] Every additional year of exclusivity therefore represents not merely increased profit for the originator firm but a significant transfer of resources from patients and public health systems to private right holders. In therapeutic areas such as oncology, HIV treatment, and rare diseases, these delays can translate into large-scale exclusion from treatment altogether.

From a competition policy perspective, evergreening also distorts the incentives of follow-on

[28] European Commission, Pharmaceutical Sector Inquiry Final Report 188–95 (2009).
[29] Carl Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, 1 INNOVATION POL'Y & ECON. 119, 120–22 (2001).
[30] Aidan Hollis, The Anti-Competitive Effects of Brand-Controlled Pseudo-Generics, 22 CAN. J.L. & TECH. 1, 4–6 (2009).

innovation. Instead of directing resources towards genuinely novel therapeutic breakthroughs, firms may rationally prefer to invest in marginal modifications that are more predictable, less risky, and more easily patentable.[31] The result is a form of innovation that is legally productive but socially ambiguous, generating extensive portfolios of rights without a commensurate increase in therapeutic value.

3.4 The Regulatory – Patent Interface and Strategic Delay

Evergreening strategies do not operate in isolation within patent offices and courtrooms. They are deeply intertwined with pharmaceutical regulatory systems. In many jurisdictions, mechanisms such as patent linkage, data exclusivity, and automatic stays of marketing approval further magnify the blocking effect of secondary patents.[32] Even in systems where such linkages are formally absent, the sheer complexity of the patent landscape can discourage or delay generic applications.

Litigation itself becomes a strategic tool in this environment. The objective is not always to win on the merits but to impose costs, uncertainty, and delay. Given the time-sensitive nature of pharmaceutical markets, even a short postponement of generic entry can generate substantial additional revenue. In this sense, evergreening is not simply a matter of patent quality. It is a broader strategy of legal risk management and market control that exploits the cumulative friction of multiple regulatory and judicial processes.

3.5 Rethinking the Normative Status of Evergreening

The persistent difficulty in regulating evergreening lies in the fact that it sits at the boundary between legitimate incremental innovation and socially harmful rent extraction. Patent law has long recognised that not all progress comes in the form of radical breakthroughs. At the same time, it has also insisted, at least in principle, that monopoly rights should be reserved for contributions that represent a real advance over existing knowledge. The challenge in the pharmaceutical sector is that this boundary has been systematically eroded by permissive patentability standards and institutional incentives that favour quantity over quality.[33]

[31] Joseph E. Stiglitz, Economic Foundations of Intellectual Property Rights, 57 DUKE L.J. 1693, 1705–08 (2008).
[32] Brook K. Baker, Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent Registration Linkage, 34 AM. J.L. & MED. 303, 309–12 (2008).
[33] Mark A. Lemley, Rational Ignorance at the Patent Office, 95 NW. U. L. REV. 1495, 1500–03 (2001).

In this context, the Indian intervention through Section 3(d) can be understood as an attempt to restore a substantive threshold of inventive merit in a domain where formal novelty alone has proven insufficient. Rather than treating evergreening as an external abuse to be corrected through competition law or compulsory licensing, the Indian approach confronts the problem at its source by questioning whether such secondary claims should generate exclusive rights at all.

4. The Legislative Design and Philosophy of Section 3(d)

The distinctiveness of the Indian response to pharmaceutical evergreening lies not in any single judicial decision but in a deliberate legislative choice to embed public interest considerations directly into the structure of patentability itself. Section 3(d) of the Patents Act represents a rare instance in which a legislature has openly acknowledged that the formal criteria of novelty and inventive step, as conventionally applied, may be insufficient to prevent the strategic extension of monopoly rights in a sector as socially sensitive as medicines. To appreciate the normative ambition of this provision, it is necessary to examine both its original form and its later transformation in the wake of India's TRIPS obligations.

4.1 The Original Section 3(d) and the Early Philosophy of Patent Exclusions

In its original incarnation, Section 3(d) was not designed with pharmaceutical evergreening in mind. The Patents Act of 1970 was a fundamentally different statute, built around a developmental vision of patent law that treated technological monopolies as instruments of industrial policy rather than as natural or inherent rights. The original Section 3(d) simply excluded from patentability the mere new use of a known substance and the mere use of a known process unless it resulted in a new product or employed at least one new reactant. This reflected a broader legislative concern with preventing routine or trivial modifications from being cloaked in the language of invention.

This approach was consistent with the overall architecture of the 1970 Act, which rejected pharmaceutical product patents altogether and confined protection to processes of limited duration. The objective was not to reward every incremental technical variation but to prevent the patent system from becoming a tool for market control rather than industrial development. The emphasis lay on diffusion, domestic capacity building, and price competition rather than on the accumulation of exclusionary rights.

The intellectual foundations of this regime can be traced to the Ayyangar Committee Report, which had warned in unambiguous terms that a strong and indiscriminate patent system in a poor country would operate not as an engine of innovation but as a mechanism of economic domination.[34] Patent law, in this vision, was never morally or politically neutral. It was an instrument of economic governance whose design had to be consciously aligned with social objectives.

4.2 The 2005 Amendment and the Birth of the Anti-Evergreening Clause

The reintroduction of pharmaceutical product patents after TRIPS placed India in a radically altered legal and economic environment. The legislature was now compelled to accept the principle of patent protection in medicines, but it retained a measure of discretion over the internal contours of patentability standards. It was within this constrained policy space that Section 3(d) was transformed from a relatively technical exclusion into a globally significant doctrinal filter.

The amended Section 3(d) provides that the mere discovery of a new form of a known substance is not patentable unless it results in the enhancement of the known efficacy of that substance, and it clarifies through an explanation that salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers, mixtures of isomers, complexes, and other derivatives are to be considered the same substance unless they differ significantly in properties with regard to efficacy. This language is striking not only for its technical specificity but also for its normative orientation. It openly signals a legislative distrust of life-cycle management strategies based on marginal modifications.

What is particularly notable is that the legislature did not rely on abstract standards such as inventive step alone to police this boundary. Instead, it introduced a substantive and sector-specific requirement tied to therapeutic efficacy. In doing so, it acknowledged that in the pharmaceutical domain, the social cost of granting unwarranted monopolies is too high to be left to the ordinary margins of patent examination error.

4.3 Parliamentary Debates and the Conscious Embrace of a Public Health Orientation

The legislative history of the 2005 amendment reveals that Section 3(d) was neither accidental

[34] Government of India, Report of the Committee on the Revision of the Patent Law (Rajagopala Ayyangar Committee Report) 21–24, 31–36 (1959).

nor merely technical. It was the subject of intense parliamentary debate, in which concerns about access to medicines, the survival of the domestic generic industry, and India's role in supplying affordable drugs to the developing world were repeatedly foregrounded.[35] Members of Parliament explicitly recognised that while TRIPS compliance was unavoidable, the form of that compliance remained a matter of sovereign choice.

The debates reflect a clear awareness of the phenomenon that would later be labelled as evergreening. Legislators spoke of the danger that multinational corporations would use minor modifications and follow-on patents to perpetually extend monopoly control over essential medicines.[36] Section 3(d) was defended as a necessary safeguard to ensure that the return of product patents did not silently reintroduce the very market structures that the 1970 Act had been designed to dismantle.

In this sense, the 2005 amendment represents a rare moment of legislative candour in patent law. Rather than pretending that patentability standards are purely technical or apolitical, Parliament openly acknowledged the distributive and ethical stakes of pharmaceutical monopolies. The provision was conceived not merely as a filter for weak patents but as a structural guarantee that the reformed patent regime would not betray its constitutional and developmental commitments.

4.4 Section 3(d) as a Philosophical Statement about the function of Patent Law

Beyond its immediate doctrinal effects, Section 3(d) embodies a deeper philosophical claim about the nature of patent rights. It rejects the idea that every incremental technical change deserves the reward of exclusivity and insists instead on a threshold of socially meaningful innovation, at least in sectors that directly implicate the right to health and life. This marks a departure from the dominant narrative in international patent law, which tends to treat patents primarily as neutral incentives for private investment.

The Indian legislature's intervention suggests a different conception of patent law as a regulatory instrument that must remain internally responsive to constitutional values and social priorities. In this view, access to medicines is not an external exception to monopoly but a core

[35] Lok Sabha Debates, Patents (Amendment) Bill, 2005, Mar. 23, 2005.
[36] Rajya Sabha Debates, Patents (Amendment) Bill, 2005, Mar. 22, 2005.

consideration that shapes the very definition of what counts as an invention in the first place.

It is this legislative philosophy that the Supreme Court would later give judicial expression to in Novartis. But even before that judicial endorsement, Section 3(d) stood as a reminder that in a constitutional democracy, the boundaries of intellectual property are not drawn solely by markets or by international agreements, but by conscious political choice.

5. *Novartis AG v. Union of India* as Transformative Patent Jurisprudence

If Section 3(d) represents the legislative conscience of the Indian patent system, *Novartis AG v. Union of India* represents its judicial articulation. The decision does not merely interpret a statutory provision. It redefines the relationship between patent law, pharmaceutical markets, and constitutional governance. In doing so, it inaugurates a distinctively Indian jurisprudence of patent restraint, one that treats monopoly in medicines not as a presumptive good to be managed at the margins, but as a social risk that must be justified at the threshold.

5.1 The Novartis Litigation and the Question Before the Court

The dispute arose from Novartis's application for a patent over the beta crystalline form of Imatinib Mesylate, a life-saving anti-cancer drug marketed as Glivec. The base compound, Imatinib, was already known, and the drug was being supplied in India at a fraction of the patented price by generic manufacturers. Novartis argued that the beta crystalline form possessed improved properties such as better flow characteristics and increased bioavailability and therefore qualified as an invention.[37]

The Patent Office rejected the application under Section 3(d) on the ground that the claimed form did not demonstrate enhanced therapeutic efficacy. The challenge that followed eventually reached the Supreme Court and presented it with a question of exceptional significance. Was Section 3(d) merely a technical filter, or did it embody a substantive policy choice to deny patents for certain categories of incremental pharmaceutical inventions?

5.2 The Supreme Court's Interpretation of "Efficacy" and the Rejection of Formalism

The Supreme Court's judgment is remarkable for its refusal to collapse the concept of invention

[37] Novartis AG v. Union of India, (2013) 6 SCC 1

into a purely formal or technical inquiry. It held that in the context of medicines, "efficacy" in Section 3(d) must be understood as "therapeutic efficacy", not merely improved physical or chemical properties. This move is jurisprudentially significant because it imports a value-laden, patient-centred standard directly into patentability analysis. The Court acknowledged that the beta crystalline form might have certain advantageous properties, but it insisted that unless these translated into enhanced therapeutic effect in treating disease, they could not justify a new monopoly. In doing so, the Court drew a clear distinction between pharmaceutical improvements that serve patients and those that primarily serve patent portfolios. Equally important is what the Court did not do. It did not treat Section 3(d) as an exception to patentability that should be narrowly construed. Instead, it treated it as an integral part of the definition of invention in the pharmaceutical field. This interpretive stance transforms Section 3(d) from a defensive provision into a constitutive principle of Indian patent law.

5.3 Novartis as a Constitutional Judgment in Disguise

Although the judgment is formally grounded in statutory interpretation, its normative structure is unmistakably constitutional. The Court repeatedly situates patent law within the broader social and economic conditions of India and refers to the dangers of unaffordable medicines in a country with deep public health vulnerabilities. Without explicitly invoking Article 21, the reasoning reflects a clear awareness that pharmaceutical monopolies operate in the shadow of the right to life and health. In this sense, Novartis marks a departure from the idea that patent law is a technocratic domain insulated from constitutional values. It affirms that in sectors affecting basic human needs, the threshold of patentability itself must be interpreted in light of social consequences. The decision thus stands as one of the rare examples in comparative patent law where a supreme court has openly acknowledged the distributive stakes of doctrinal choices.

5.4 The Consolidation of the Novartis Doctrine in Subsequent Indian Cases

The significance of Novartis lies not only in its own holding but in the jurisprudential path it set for lower courts and patent authorities. In *F. Hoffmann-La Roche Ltd. v. Cipla Ltd*., the Delhi High Court adopted a sceptical approach to secondary pharmaceutical patents and emphasised that incremental modifications must be scrutinised with particular care in a market where access concerns are paramount.[38] Although the case was primarily about infringement

[38] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., (2009) 40 PTC 125 (Del).

and interim injunctions, its reasoning reflects a broader judicial unease with monopolistic overreach in essential medicines.

In *Bayer Corporation v. Union of India*, which concerned India's first compulsory licence for the cancer drug Nexavar, the legal system took the logic of Novartis one step further by demonstrating that even a valid patent does not exist in isolation from public interest considerations.[39] The Controller's order and its subsequent judicial affirmation made it clear that working of patents, affordability, and reasonable public requirements are not peripheral concerns but central to the legitimacy of pharmaceutical monopolies.

Similarly, in *Ajanta Pharma Ltd. v. Allergan Inc*., the Delhi High Court refused to mechanically enforce secondary patent claims where the balance of convenience and public interest weighed heavily in favour of generic access.[40] The case illustrates how the post-Novartis judicial mindset treats pharmaceutical patent enforcement not as a routine property dispute but as a matter requiring heightened scrutiny.

In *Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals*, while the Court granted an injunction in favour of the patentee, it nonetheless engaged in a far more detailed and demanding analysis of inventive step and therapeutic contribution than would have been typical in earlier eras.[41] This suggests that Novartis did not abolish pharmaceutical patents but recalibrated the level of justification required to sustain them.

Even at the level of the Intellectual Property Appellate Board and Patent Office practice, the influence of Novartis has been visible in a more rigorous application of Section 3(d) and a greater willingness to reject claims directed at new forms, new uses, and minor modifications of known substances.[42] While institutional capacity constraints remain, the doctrinal direction is unmistakable.

5.5 From Patent Exceptionalism to Patent Responsibility

Taken together, these cases reveal a coherent, if still evolving, judicial philosophy. Indian courts no longer treat pharmaceutical patents as ordinary commercial assets. They are increasingly

[39] Bayer Corp. v. Union of India, (2014) 59 PTC 113 (Bom).
[40] Ajanta Pharma Ltd. v. Allergan Inc., 2013 SCC OnLine Del 1688.
[41] Merck Sharp & Dohme Corp. v. Glenmark Pharm. Ltd., (2015) 60 PTC 1 (Del).
[42] Intellectual Prop. App. Bd., Order No. 205 of 2012 (various post-Novartis oppositions and revocations).

seen as regulatory privileges that must be justified not only in terms of technical novelty but in terms of social purpose. This does not mean that India has adopted an anti-patent stance. Rather, it has rejected patent exceptionalism, the idea that patent rights should be insulated from the ordinary disciplines of constitutional and public interest reasoning. In its place, it has begun to articulate a model of patent responsibility, in which the grant and enforcement of monopoly rights in medicines are treated as matters of public trust. In this sense, Novartis is not merely a leading case on Section 3(d). It is the constitutional moment of Indian pharmaceutical patent law. It signals that in a democratic society marked by deep inequality and pressing health needs, the legitimacy of intellectual property cannot rest on formal compliance with international standards alone. It must also answer to the demands of justice, accessibility, and human welfare.

6. Does Section 3(d) Discourage Innovation?

Perhaps the most persistent criticism levelled against Section 3(d) is that it allegedly undermines pharmaceutical innovation by denying protection to incremental improvements and by injecting legal uncertainty into patentability standards. According to this view, a strict efficacy threshold discourages investment in research and development and signals that India is hostile to innovation-driven growth. This argument, often advanced by multinational pharmaceutical firms and their policy advocates, rests on a particular conception of innovation and on an equally particular understanding of what patent law is meant to reward. Both deserve closer scrutiny.

6.1 The Industry Narrative of Innovation Suppression

The conventional industry position treats incremental innovation as the backbone of pharmaceutical progress. Many therapeutic advances, it is argued, do not come in the form of radical breakthroughs but through gradual refinements in safety profiles, dosing regimens, and patient compliance. From this perspective, any legal rule that raises the threshold for patentability beyond formal novelty and inventive step risks choking off precisely the kind of cumulative progress on which modern medicine depends.[43]

This argument draws strength from the undeniable reality that drug development is a long, uncertain, and capital-intensive process. Failures vastly outnumber successes, and the revenues

[43] Henry Grabowski, Patents, Innovation and Access to New Pharmaceuticals, 5 J. INT'L ECON. L. 849, 852–55 (2002).

from a few blockbuster drugs often cross-subsidise a large number of unsuccessful research projects.[44] Within this economic structure, the predictability and breadth of patent protection are said to be essential for sustaining private investment.

Yet this narrative tends to conflate two distinct questions. The first is whether incremental improvements should be encouraged. The second is whether they should be rewarded with new twenty-year monopolies. Section 3(d) does not deny the value of incremental innovation. It denies only that every such modification deserves the legal and economic privileges associated with patent exclusivity.

6.2 Royalty-Seeking, Strategic Patenting, and the Distortion of Innovation Incentives

From a political economy perspective, evergreening is best understood not as a marginal phenomenon but as a predictable response to a system that over-rewards exclusivity relative to therapeutic value. When firms can obtain substantial returns by extending the life of existing products rather than by discovering genuinely new treatments, rational investment strategies will shift accordingly.[45] The result is not an absence of innovation but a skewed pattern of innovation that privileges legal defensibility over clinical significance.

This dynamic is visible in the proliferation of so-called "me-too" drugs and marginal reformulations that offer little or no additional therapeutic benefit over existing treatments while consuming substantial research, regulatory, and marketing resources.[4] In such an environment, the social opportunity cost of permissive patentability standards is not merely higher prices. It is the diversion of scientific effort away from unmet medical needs and towards commercially safer projects. Section 3(d) attempts to intervene in this incentive structure by drawing a normative line between innovations that change therapeutic outcomes and those that merely rearrange existing knowledge into new legal claims. In doing so, it does not suppress research. It seeks to redirect it.

6.3 Empirical Uncertainty and the Limits of the Innovation-Chilling Argument

A striking feature of the debate around Section 3(d) is the weakness of the empirical evidence supporting claims of innovation suppression. Despite repeated warnings that India's patent

[44] Christopher P. Adams & Van V. Brantner, Estimating the Cost of New Drug Development, 25 J. HEALTH ECON. 420, 422–27 (2006).
[45] Mariana Mazzucato, The Entrepreneurial State: Debunking Public vs. Private Sector Myths 198–203 (2013).

regime would deter investment, the country has continued to attract substantial pharmaceutical research activity, particularly in clinical trials, contract research, and process development. At the same time, the global pharmaceutical industry continues to face a widely acknowledged productivity crisis, with declining rates of genuinely novel drug approvals despite ever-expanding patent portfolios.[46]

This suggests that the relationship between patent strength and meaningful innovation is far more complex than industry rhetoric often implies. Stronger and more numerous patents do not automatically translate into better therapeutic outcomes. They may, in fact, contribute to what some scholars have described as an "innovation illusion", a system that generates an abundance of legal rights but a scarcity of socially transformative treatments.[47]

Section 3(d), in this context, can be seen as a modest corrective rather than a radical experiment. It does not dismantle the patent system. It merely insists that in one of the most socially sensitive sectors of the economy, the grant of monopoly should be more tightly linked to demonstrable public benefit.

6.4 Innovation as a Constitutional and Developmental Concept

The deeper disagreement underlying the Section 3(d) controversy is not about patent doctrine but about the meaning of innovation itself. In the dominant global discourse, innovation is often equated with private investment activity and the accumulation of proprietary assets. In a developing country context, however, innovation has a broader and more complex meaning. It includes not only the discovery of new molecules but also the improvement of access, the adaptation of technologies to local conditions, and the efficient delivery of existing treatments to underserved populations.[48] From this perspective, a patent regime that maximises the number of exclusive rights while restricting access to essential medicines may be innovative in a narrow commercial sense but regressive in social terms. Section 3(d) embodies a different vision, one in which innovation policy is subordinated to constitutional commitments to health, life, and equitable development.

[46] U.S. Food & Drug Administration, Novel Drug Approvals for 2022, FDA Report (2023).
[47] Michael Heller & Rebecca Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 SCIENCE 698, 698–701 (1998).
[48] World Health Organization, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health 15–21 (2006).

6.5 Reframing the Debate from Incentives to Justification

Ultimately, the question is not whether the pharmaceutical industry should be rewarded. It is whether the reward of monopoly should be granted without a demanding inquiry into what is being rewarded. Section 3(d) does not assume that all innovation is equal. It requires patentees to justify their claims to exclusivity in terms that go beyond formal chemical difference and extend to real therapeutic contribution. In this sense, the provision does not chill innovation. It disciplines rent-seeking. It does not close the door to incremental progress. It simply refuses to convert every marginal improvement into a new legal barrier against competition. If this approach makes certain business models less attractive, that is not a failure of patent policy. It is its success.

7. Comparative Perspectives from the United States and the European Union

A comparative view of pharmaceutical patent law in the United States and the European Union reveals that India's experiment with Section 3(d) is not an anomaly in its concern for overbroad monopolies. What is exceptional is the location at which India chooses to intervene. While US and EU systems largely attempt to control evergreening through litigation standards, regulatory competition rules, and post-grant enforcement, India has chosen to discipline the problem at the threshold of patentability itself. This difference in institutional design has profound consequences for both market structure and access to medicines.

7.1 The United States: From Patent Expansion to Judicial Retrenchment

For several decades, the United States maintained one of the most permissive environments for pharmaceutical patenting. The combination of broad subject matter eligibility, a relatively low bar for non-obviousness, and regulatory mechanisms such as patent linkage under the Hatch-Waxman Act created ideal conditions for the proliferation of secondary patents. The result was a dense ecology of life-cycle management strategies built around blockbuster drugs.

The Supreme Court's decision in *KSR International Co. v. Teleflex Inc.* marked an important turning point by rejecting rigid tests of non-obviousness and restoring a more flexible and demanding inquiry into inventive step.[49] Although the case did not concern pharmaceuticals

[49] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

directly, its effects were quickly felt in chemical and life sciences patents, where routine modifications could no longer rely on formalistic arguments to survive scrutiny.

In *Mayo Collaborative Services v. Prometheus Laboratories*, the Court further narrowed the scope of patentable claims by insisting that the mere application of natural laws using conventional steps does not constitute an invention.[50] This reasoning, later reinforced in *Association for Molecular Pathology v. Myriad Genetics*, signalled a broader judicial unease with the expansion of exclusive rights over discoveries that do not reflect genuine technical contribution.[51]

Within the pharmaceutical field, the consequences of evergreening have been addressed more directly through competition and antitrust litigation. In *FTC v. Actavis, Inc.*, the Supreme Court held that "pay-for-delay" settlements between brand-name and generic manufacturers could violate antitrust law even when they operate within the formal scope of patent rights.[52] The judgment is significant because it recognises that patent law cannot be treated as an island insulated from market power analysis, especially in a sector where strategic behaviour can postpone competition for years.

Lower courts have increasingly scrutinised secondary patents with greater scepticism. In *In re Omeprazole Patent Litigation*, for example, complex formulation patents were subjected to searching inquiry into obviousness and enablement.[53] More recently, decisions involving drugs such as Lyrica and Restasis have demonstrated a growing willingness to invalidate follow-on patents that appear designed primarily to block generic entry rather than to reward genuine therapeutic advances.[54] Yet despite this judicial tightening, the American system continues to rely largely on ex post correction through litigation. The structural incentives for dense patenting remain intact, and the cost and uncertainty of legal challenges continue to function as barriers to timely generic entry.

7.2 The European Union: Technical Rigour and Regulatory Supplementation

The European patent system presents a somewhat different picture. The European Patent

[50] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).
[51] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[52] FTC v. Actavis, Inc., 570 U.S. 136 (2013).
[53] In re Omeprazole Patent Litig., 536 F.3d 1361 (Fed. Cir. 2008).
[54] Allergan, Inc. v. Teva Pharm. USA, Inc., 754 F.3d 952 (Fed. Cir. 2014) and Fed. Trade Comm'n v. AbbVie Inc., 976 F.3d 327 (3d Cir. 2020).

Convention has long insisted on a relatively strict approach to inventive step, particularly in the chemical and pharmaceutical fields, through the problem-solution approach developed by the Boards of Appeal of the European Patent Office. Decisions such as *AgrEvo* and *Takeda* have emphasised that obvious variations and routine optimisations do not merit patent protection.

In *Bristol-Myers Squibb v. Baker Norton*, the English courts applied these principles to invalidate patents that attempted to claim minor modifications without a demonstrable technical contribution.[55] Similarly, in *Generics (UK) v. Lundbeck*, European courts confronted the strategic use of secondary patents and settlement agreements designed to delay competition, ultimately treating such practices as potential abuses of dominant position under EU competition law.[56]

The Court of Justice of the European Union has played a particularly important role in integrating competition policy into the governance of pharmaceutical monopolies. In *AstraZeneca v. Commission*, the Court upheld findings that the strategic misuse of regulatory and patent procedures could constitute an abuse of dominance, even when formal legal rights were involved.[57] This reasoning echoes, at a systemic level, the insight that the social legitimacy of patent rights depends on how they are used, not merely on how they are granted.

At the same time, the European system has developed mechanisms that arguably facilitate a different form of life-cycle extension. Supplementary Protection Certificates, designed to compensate for regulatory delays, often extend effective exclusivity well beyond the nominal patent term. Cases such as *Neurim Pharmaceuticals* and *Seattle Genetics* illustrate how complex and contested the boundaries of these extensions have become.[58] While these instruments are formally justified as innovation incentives, their cumulative effect is to reinforce the structural advantages of originator firms.

7.3 Structural Differences and the Indian Contrast

What distinguishes the Indian approach from both the US and EU models is not the concern

[55] Bristol-Myers Squibb Co. v. Baker Norton Pharm. Inc. [2001] RPC 1 (CA).
[56] Case C-591/16 P, Gen. Elec. Co. v. Comm'n (Lundbeck), ECLI:EU:C:2021:243.
[57] Case C-457/10 P, AstraZeneca AB v. Comm'n, ECLI:EU:C:2012:770.
[58] Case C-130/11, Neurim Pharm. (1991) Ltd v. Comptroller Gen., ECLI:EU:C:2012:489 and Case C-471/14, Seattle Genetics Inc. v. Österreichisches Patentamt, ECLI:EU:C:2015:659.

with evergreening but the level at which that concern is operationalised. In the United States and Europe, the system tolerates the accumulation of large secondary patent portfolios and then relies on litigation, competition law, or regulatory review to trim their effects. This approach is costly, uncertain, and often arrives too late to prevent significant delays in generic entry. India, by contrast, attempts to prevent such portfolios from arising in the first place by imposing a demanding substantive threshold at the stage of patentability. Section 3(d) does not wait for courts or competition authorities to correct excesses after monopoly has already been granted. It asks, at the outset, whether the claimed invention is the kind of advance that deserves monopoly at all in a sector that directly affects the right to life.

From a comparative perspective, this is not a rejection of innovation. It is a different institutional answer to the same problem that US and EU courts have been struggling to manage through increasingly complex and expensive ex post controls. The Indian model shifts the burden of justification forward in time and places it squarely on the patentee.

7.4 Convergence in Concern, Divergence in Technique

Across jurisdictions, one can observe a growing judicial and regulatory discomfort with the unchecked expansion of pharmaceutical patent portfolios. The language of obviousness, inventive step, abuse of dominance, and anticompetitive settlements reflects a shared recognition that the patent system, left to its own devices, tends to overproduce exclusivity in this sector. The divergence lies in technique rather than in objective. The United States and the European Union attempt to civilise pharmaceutical monopolies after they have been created. India attempts to civilise them before they come into existence. Whether one approach is normatively superior may ultimately depend on institutional capacity and political economy. What is clear is that Section 3(d) is not an outlier in its suspicion of evergreening. It is simply more honest about where the real battle over pharmaceutical monopoly must be fought.

8. Access to Medicines as a Constitutional and Human Rights Imperative

The debate over pharmaceutical patents cannot ultimately be resolved within the closed logic of innovation policy alone. It is inseparable from a more fundamental legal and moral question, namely whether access to life-saving medicines is to be treated as a matter of market allocation or as a matter of right. In India, this question has acquired a distinctly constitutional character. Over several decades, the Supreme Court has transformed the right to life under Article 21

from a negative guarantee against state action into a positive entitlement to the conditions necessary for a life of dignity. Within this jurisprudential framework, access to healthcare and essential medicines is no longer a matter of charity or policy discretion. It is a component of constitutional obligation.

8.1 The Right to Health and the Expansion of Article 21

The Indian Supreme Court has consistently held that the right to life does not mean mere animal existence but includes the right to live with human dignity and all that goes along with it.[59]Building on this foundation, the Court has explicitly recognised health as an integral part of the right to life. In *Consumer Education and Research Centre v. Union of India*, the Court held that the right to health and medical care is a fundamental right of workers because it is essential to the meaningful enjoyment of life.[60] This reasoning was later extended beyond the employment context to the general population.

In *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, the Court went further and held that the failure of the State to provide timely medical treatment to a person in need amounts to a violation of Article 21.[61] The judgment is particularly important because it reframes healthcare not as a matter of resource-dependent policy choice but as a constitutional duty whose breach can attract judicial scrutiny.

These decisions establish a crucial normative baseline. If access to healthcare is a constitutional right, and if medicines are an indispensable component of healthcare, then the legal regime governing the production and pricing of medicines cannot be treated as constitutionally neutral. Patent law, in this domain, becomes part of the infrastructure through which the State either fulfils or frustrates its fundamental obligations.

8.2 Essential Medicines, State Obligation, and Market Structure

The Indian courts have also recognised that the State's duty under Article 21 is not exhausted by the mere existence of hospitals or doctors. In *State of Punjab v. Mohinder Singh Chawla*, the Supreme Court held that the right to life includes the right to health and that the State has

[59] Francis Coralie Mullin v. Adm'r, Union Territory of Delhi, (1981) 1 SCC 608.
[60] Consumer Educ. & Research Ctr. v. Union of India, (1995) 3 SCC 42.
[61] Paschim Banga Khet Mazdoor Samity v. State of W.B., (1996) 4 SCC 37.

an obligation to provide medical assistance to every person.[62] The logic of this line of cases implies that when life-saving treatment exists but is rendered inaccessible due to price barriers, the constitutional promise is hollowed out in practice.

This is where the structure of pharmaceutical markets becomes constitutionally salient. Patent-induced monopolies are not merely private commercial arrangements. They are legal privileges created and enforced by the State. When such privileges result in prices that place essential medicines beyond the reach of large segments of the population, the resulting deprivation cannot be viewed as a purely private misfortune. It is a consequence of a regulatory choice for which the State bears constitutional responsibility. The Court's jurisprudence on socio-economic rights has repeatedly emphasised that resource constraints do not absolve the State of its core obligations. While the exact contours of enforcement may vary, the basic commitment to protect life and health is non-negotiable.[63] This has direct implications for how the State designs and interprets its patent laws.

8.3 International Human Rights Law and the Right to Medicines

The constitutional status of access to medicines in India is reinforced by India's international obligations. The International Covenant on Economic, Social and Cultural Rights recognises the right of everyone to the highest attainable standard of physical and mental health.[64] The Committee on Economic, Social and Cultural Rights has clarified that this right includes access to essential medicines as defined by the World Health Organization.[65]

These obligations do not require States to manufacture all medicines themselves. They do, however, require States to ensure that their legal and economic systems do not create unreasonable barriers to access. Intellectual property regimes are explicitly included within the scope of policies that must be aligned with human rights commitments. The former UN Special Rapporteur on the Right to Health has repeatedly warned that excessive patent protection in the pharmaceutical sector can be incompatible with States' human rights duties.[66] In this light, TRIPS compliance cannot be treated as a complete answer to constitutional or human rights

[62] State of Punjab v. Mohinder Singh Chawla, (1997) 2 SCC 83.
[63] Navtej Singh Johar v. Union of India, (2018) 10 SCC 1 (on dignity as core to Article 21).
[64] International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.
[65] U.N. Comm. on Econ., Soc. & Cultural Rts., General Comment No. 14, ¶ 43(d), U.N. Doc. E/C.12/2000/4 (2000).
[66] U.N. Special Rapporteur on the Right to Health, Report on Access to Medicines, U.N. Doc. A/61/338 (2006).

concerns. International trade obligations do not displace the State's primary responsibility to protect life and health. Rather, they must be interpreted and implemented in a manner consistent with that responsibility.

8.4 Patents, Proportionality, and Constitutional Justification

Once access to medicines is understood as a constitutional and human rights imperative, the legal status of pharmaceutical patents must be re-evaluated. Patents are not natural rights. They are statutory privileges granted for instrumental reasons. In constitutional terms, they represent a restriction on competition and, indirectly, on access. Such restrictions require justification. Indian constitutional law has increasingly adopted a proportionality-based approach to rights adjudication. Under this framework, any measure that limits a fundamental right must pursue a legitimate aim, must be suitable to achieve that aim, must be necessary in the sense that no less restrictive alternative is available, and must strike a fair balance between competing interests.[67] Although patent law is rarely analysed explicitly in these terms, the logic is inescapable. When patent monopolies in medicines result in the exclusion of large populations from life-saving treatment, the burden of justification becomes particularly heavy.

Section 3(d) can be understood as a legislative attempt to apply a form of proportionality reasoning at the stage of patent grant itself. By insisting that only those incremental pharmaceutical inventions that demonstrate enhanced therapeutic efficacy deserve new monopolies, the law seeks to ensure that the social cost imposed by exclusivity is justified by a corresponding social benefit.

8.5 From Charity to Entitlement

The most important consequence of framing access to medicines as a constitutional and human rights imperative is that it shifts the discourse from charity to entitlement. Patients are no longer passive recipients of benevolence, whether from the State or from pharmaceutical companies. They are rights-holders whose claims impose duties on legal and economic institutions. In this normative universe, patent law cannot remain a morally insulated domain. It becomes part of the constitutional architecture through which society decides how life-saving resources are allocated. The Indian approach, with all its imperfections, represents a serious attempt to take this reality into account. It treats pharmaceutical patents not as ends in themselves, but as

[67] K.S. Puttaswamy v. Union of India, (2017) 10 SCC 1.

regulatory tools that must remain subordinate to the most basic commitment of any constitutional order, which is the preservation of human life and dignity.

9. Conclusion: Patent Law, Public Power, and the Future of Pharmaceutical Governance

This paper has argued that the Indian response to pharmaceutical evergreening represents not a technical deviation from global patent norms but a principled attempt to reassert democratic control over one of the most socially consequential areas of economic regulation. The debate over Section 3(d) is ultimately not about chemical forms, dosage regimes, or drafting techniques. It is about whether legal systems are willing to acknowledge that in sectors where monopoly power determines access to life-saving resources, patent law cannot remain morally agnostic.

The Indian experience demonstrates that it is possible to design a patent regime that complies with international obligations while still preserving meaningful space for public interest reasoning at the very core of patentability. By relocating the access-to-medicines concern from the margins of enforcement into the architecture of the invention threshold itself, the law alters the political economy of pharmaceutical monopolies in a structurally significant way. It does not rely solely on downstream corrections through compulsory licensing or price regulation. It insists on justification before exclusivity is granted.

At the same time, this model should not be romanticised. It operates within a global system that continues to exert strong centripetal pressures towards stronger and more numerous exclusive rights. Trade negotiations, regulatory convergence, and evolving corporate strategies all generate constant incentives to dilute substantive scrutiny while preserving formal compliance. The durability of the Indian approach will therefore depend not only on statutory language or judicial precedent, but on institutional capacity, administrative courage, and political commitment. What emerges most clearly from this analysis is that pharmaceutical patent law can no longer be treated as a specialised subfield insulated from constitutional and developmental choices. It is a site where the State actively structures life chances through the allocation of legal power. Once this is acknowledged, questions of patentability, enforcement, and regulatory design must be evaluated not only in terms of efficiency or investment signals, but in terms of legitimacy, proportionality, and social consequence.

The Indian experiment also holds broader implications for global intellectual property governance. It suggests that the future of patent law in critical sectors may lie not in ever more complex mechanisms to manage monopolies after they are created, but in a renewed willingness to ask more demanding questions about which monopolies should exist at all. This is not an argument against innovation. It is an argument for restoring coherence between innovation policy and human welfare. Finally, this study opens several important avenues for future research. First, there is a need for careful empirical work on how Section 3(d) has actually reshaped research strategies, patent filing behaviour, and pricing outcomes over time. Second, comparative constitutional analysis could examine whether similar public-interest thresholds could be normatively justified in other fields such as agricultural biotechnology or medical devices. Third, the growing interaction between patent law, competition law, and procurement policy calls for an integrated theory of pharmaceutical governance rather than siloed doctrinal analysis. Fourth, the institutional design of patent offices and their epistemic capacity to evaluate therapeutic claims remains an under-theorised but crucial issue.

The central lesson of the Indian experience is not that patent law should be hostile to markets, but that it should be honest about power. In the domain of medicines, where the stakes are measured in lives rather than in abstract welfare curves, legal systems must remain willing to say that not every technically new thing deserves to become a legally exclusive one. That willingness is not an obstacle to progress. It is one of its conditions.