BALANCING INTELLECTUAL PROPERTY RIGHTS AND PUBLIC HEALTH: AN EXAMINATION OF SECTION 3(D) OF THE INDIAN PATENTS ACT

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ABSTRACT

The practice of patent evergreening, where drug innovators prolong monopolies by making incremental changes to established medicines, is a persistent threat to balancing intellectual property rights with public health needs. Section 3(d) of the Indian Patents Act, 1970, enacted as part of India's implementation of the TRIPS Agreement, is a unique legislative approach to this problem. By mandating demonstrable improvement in curative effect for the grant of patents for new forms of old drugs, Section 3(d) acts as a substantive gatekeeper against trivial patents as well as a protector of access to medicines. The article critically examines the making, construction, and implications of Section 3(d) as part of India's overall patent regime. Analyzing path-breaking judicial pronouncements such as Novartis AG v. Union of India (2013), the paper identifies how Indian law has built a robust pro-public health narrative that resists multinational pharma tactics of incremental innovation. The study also contrasts India's policy with United States and European Union patent standards, where broader definitions of novelty and utility generally permit secondary patents. While Section 3(d) has been welcomed as a model for developing countries that desire to balance innovation with access, it has also faced criticism for potentially discouraging incremental research and for vagueness in outlining "enhanced efficacy." The article explores that Section 3(d) is a bold but contentious attempt at reconciliation between innovation and social justice. It highlights the importance of greater direction to discriminate between true therapeutic development and minor changes and situates the provision in the global context of access to drugs. Lastly, the analysis reaffirms Section 3(d)'s role as a pioneering legal response to evergreening, acknowledging the continued competition between intellectual property protection and the needs of public health.

Keywords: Ever greening, patents, efficacy, AYUSH, sec 3(d), Novaratis AG v UOI.

INTRODUCTION

The intersection of intellectual property rights (IPRs) and public health is perhaps the most contentious field of international law[1]. Nowhere is the conflict more apparent than in the field of pharmaceutical patents, where the preservation of innovator monopoly rights clashes with the global imperative of providing access to medicines affordably[2]. The enforcement of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization in 1995 fundamentally shifted this landscape by ensuring a baseline of intellectual property protection, product patents for drugs among them[3].

India, being a developing country with a robust domestic generic industry, was at the eye of this change[4]. For long, the Indian Patents Act of 1970 had granted only process patents in pharmaceuticals and agrochemicals, allowing local companies to produce generic medicines and making India the "pharmacy of the developing world[5]." But in 2005, India needed to introduce product patents as a measure to meet TRIPS commitments.

While this shift was meant to bring Indian patent law in line with the global standard, it also raised deep concerns regarding access to affordable medicine at home and across the Global South. In order to counter these apprehensions, the Indian legislature incorporated various safeguards in its regime of patent protection, and Section 3(d) of the Patents Act is most characteristic and contentious of these safeguards. Section 3(d) provides that mere discovery of a new form of a known substance does not qualify as an invention, unless such discovery reveals an enhancement in the known efficacy of such substance. Its purpose is to prevent "evergreening," i.e., the practice of pharmaceutical companies extending patent monopolies by minor modifications to initial drugs without any real therapeutic benefit.

Section 3(d)'s international importance was consolidated through the landmark Novartis AG v. Union of India (2013) judgment, whereby India's Supreme Court upheld rejection of patent on the beta-crystalline form of Imatinib Mesylate (Gleevec) by holding it did not establish

[1] CARLOS M. CORREA, *INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS* 3–8 (2000).
[2] Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 AM. J. INT'L L. 317, 317–18 (2005).
[3] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27, 33, Apr. 15, 1994, 1869 U.N.T.S. 299.
[4] SUDIP CHAUDHURI, *THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES* 25–47 (2005).

enhanced therapeutic efficacy. Its ruling was hailed overseas as good news for public health and access to medicine, repositioning India as an exporter of cheap generics. It, nevertheless, elicited criticism of discouraging incremental innovations, triggering confusion regarding patent quality, and loss of investor confidence. Scholarship and jurisprudence hitherto have concentrated on interpreting "efficacy" in Section 3(d)[6]. Duly important, this specific focus disregards one set of wider and unresolved challenges posed by the provision. Firstly, Section 3(d) extends beyond pharmaceuticals and applies equally to areas like biotechnology, agrochemicals, and medical devices, but outside pharmaceuticals, it remains understudied and unevenly implemented. Secondly, in establishing an elevated post of patentability, Section 3(d) could have an instance-deterring effect on incremental innovations, which, as not being radically new, may nevertheless enhance patient compliance, medicine stability in tropical regions, or drug-delivery systems. These increments, being small-scale, can have high social and health returns. . Thirdly, unevenness in testing practices by the Indian Patent Office has led to uneven holdings and uncertainty for petitioners, thereby undermining legal certainty and curbing investment. Finally, while Section 3(d) is celebrated as a public health guardian, empirical data on its de facto impact on price affordability and access to medications is meager and inconclusive. These unresolved problems comprise the research issue of this study: in addition to the debate over "efficacy," Section 3(d) presents important challenges to its extension outside pharmaceuticals, to a chilling effect upon incremental innovation, and to the lack of standardized examining practices. These problems in aggregate endanger legal certainty, investors' confidence, and potentially, the very access-to-medicines purposes to which the provision was meant to serve[7]. The objectives of the current study are therefore multi-faceted: to trace the historical evolution and legislative intent of Section 3(d); to analyze its judicial interpretation and its contribution to avoiding evergreening; to make a comparative study of standards of patentability in the United States, the European Union, and India; to analyze challenges arising from the application of the provision outside the pharmaceutical industry; to gauge its effect on incremental innovation, investor confidence, and access to drugs; and to reach policy suggestions for enhancing clarity, predictability, and effectiveness of the Indian patent system.

The paper makes a study by a doctrinal and comparative approach. It involves close reading of

[6] Novartis AG v. Union of India, (2013) 6 S.C.C. 1 (India).
[7] Arti K. Rai, Interpretation of the Section 3(d) Standard in India: Implications for Innovation and Access, 12 NW. J. TECH. & INTELL. PROP. 376, 380–82 (2014).

legislative documents, court decisions, and legislative history, with comparative examination of patentability standards in jurisdictions. Primary materials include the Indian Patents Act, the TRIPS Agreement, case law, and parliamentary debates, while secondary materials include scholarly papers, commentaries, and policy reports. The study does not undertake an empirical quantitative analysis of innovation or access patterns, yet it employs available information and reports to inform its qualitative assessment[8]. The research is confined to Section 3(d) in the broader context of Indian patent law, but within the sphere of pharmaceuticals and generally as it applies in other sectors too. The research is bounded by the employed data and the interpretive nature of doctrinal analysis and thus to subsequent technological and legal developments.

BEYOND EFFICACY

Whilst debate regarding effectiveness dominates scholarship, relatively less effort has been devoted to more broad-based operational and policy challenges of Section 3(d)[9]. As one example, patent interpreting and examining irregularities in the Indian Patent Office have been cited in various works (Rai & Jayadev, 2017; Mukherjee, 2018). Applicants of patents most frequently remain uncertain as to whether their products would evince "improved efficacy" and, as such, could induce delays and legal controversies.

Moreover, scholars note potential chilling effect on incremental innovation in biotechnology, drug devices, and agrochemicals can also be said not necessarily to fall within the strict criterion of efficacy but constitute technological development and treatment of the patient (Abbott, 2007; Correa, 2002) The writings note a need for more express guidelines and sectoral standards to ensure Section 3(d) will not have an unintended negative impact on socially valuable innovation[10].

Scholarship on Section 3(d) of the Indian Patents Act and the larger question of patent evergreening spans a broad range of views[11]. Herbal Pharmaceutical Patent Protection: Illustrative Evidence on Prosecution Stages and Section 3(d) Implication of Indian Patent Act

[8] WORLD INTELLECTUAL PROP. ORG., WORLD INTELLECTUAL PROPERTY REPORT (2018).
[9] Srividhya Ragavan, The Novartis Decision: Implications for Pharmaceutical Patent Law in India, 46 GEO. WASH. INT'L L. REV. 1, 25–30 (2013).
[10] Frederick M. Abbott, Innovation and the Pharmaceutical Industry Under TRIPS, in UNCTAD-ICTSD PROJECT ON IPR AND SUSTAINABLE DEVELOPMENT 12–18 (2007)
[11] Shamnad Basheer & Prashant Reddy, The "Efficacy" of Indian Patent Law: Ironing Out the Creases in Section 3(d), 5 SCRIPTED 232, 235–40 (2008).

by Sharma and Ravikumar goes into the hitherto unrepresented connection between traditional knowledge, herbal drugs, and intellectual property, highlighting a scarcity of empirical data on community-based innovations and a treatment thereof by Section 3(d)[12]. Subham Chauhan's Exploring the Controversial Practice of Patent Evergreening discusses tactics used during prosecution by drug majors for the perpetration of monopoly by means of evergreening, exemplified by Gleevec and Emtriva, and though it spotlights Section 3(d) as a disincentive, it does not take into account the impact thereof on AYUSH drug products. In Balancing Innovation and Access: Evergreening, IPR, and Competition Law in the Indian Pharmaceutical Industry, Chandana, Rajapur, and Subbaiah discuss the interplay between patent law and competition law, especially during the pandemic days of COVID-19, but not the inconsistencies between how the term "efficacy" has been used by the Examining Regime. L. Ashish Kumari and K. Sita Manikyam's Evergreening of Patents: A Study on Legal Position in India and Dherya Maheswari's Exploitation of Patents: A Study of Evergreening in the Pharmaceutical Domain both scrutinize the Novartis case and the TRIPS regime but not the reality of enforcement by the Indian patent office. Kriti Singh's Critical Analysis of Section 3(d) of the Indian Patent Act, 1970 points out the uncertainties regarding "enhanced efficacy" and the arbitrariness inherent in the applicability thereof, whereas Niloufer Sohrabji and Kaitlyn Maloney's Section 3(d) and Pharmaceutical Patents in India employ a database of 500 patents for empirical demonstration of the impact of the provision but without specifying how efficacy must uniformly come to be read. Comparative studies, such as Evergreening in Pharmaceuticals: "Gaming" the Patent System (Tesi di Laurea) and John R. Thomas's Patent Evergreening: Issues in Innovation and Competition, contrast standards between the United States, India, and the EU, highlighting systemic incentives but gaps relative to afford-ability and therapeutic efficacy. Finally, Imran Ahad's Ever-Greening of Patents of Drugs and Right to Health: A ConflictingInterest associates the right of health with the ever-greening but uses the Novartis case and does not suggest reforms for the fine-tuning of Section 3(d)[13]. As a whole, these studies solidify Section 3(d) as a special provision against the ever-greening but affirm gaps relative to the provision's operational consistency at the level of the real word, for AYUSH and incremental innovation uses, as well as empirical testing for the provision's real-word

[12] Rakesh Sharma & K. Ravikumar, Herbal Pharmaceutical Patent Protection: Illustrative Evidence on Prosecution Stages and Section 3(d) Implication of Indian Patent Act, 10 J. INTELL. PROP. RTS. 312, 315–22 (2015).

[13] Imran Ahad, Ever-Greening of Patents of Drugs and Right to Health: A Conflicting Interest, 9 INT'L J. HUM. RTS. & CONST. STUD. 55, 60–68 (2016).

consequences.

STATEMENT OF PROBLEM

The bulk of current scholarship regarding Section 3(d) of the Indian Patents Act concentrates unilaterally upon "therapeutic efficacy" for drugs, frequently ignoring the provision's wider applicability across many technological fields and the detailed impact upon incremental innovation as well as investor confidence. Additionally, procedural inconsistencies during the examination for patents remain unadequately scrutinized, creating long-standing legal uncertainty for petitioning parties. Though there does exist comparative research utilizing other jurisdictions, few convert such research into actionable and realizable policy solutions unique to the situation of India. As a result, a compelling research need exists for a wide-ranging study which goes beyond the efficacy question and critically questions Section 3(d)'s broader implications for innovation, legal clarity, and public health policy. Though intended as an anti-evergreening provision for public health, Section 3(d) now lies at the center of a multifaceted dispute: extension into non-pharmaceutical fields, perceived incremental innovation constraint, and unequal practice jeopardizing legal certainty as well as investor confidence. This latter eventuality eventually undermines the provision's original intent for increased access for cheaper medicines and positions Section 3(d) at the innovation-public health-TRIPS obligations for India crossroads.

RESEARCH QUESTIONS

Whether Section 3(d) of the Indian Patents Act has been applied and interpreted consistently by courts and patent authorities, or whether ambiguities in practice have created legal uncertainty.

To what extent Section 3(d) discourages incremental innovation and affects investor confidence, thereby influencing R&D and technology development in India.

How far India’s approach under Section 3(d) differs from the patentability standards in the United States and the European Union, and what lessons emerge from such a comparative analysis.

In what ways reforms in policy or patent examination guidelines could strengthen the effectiveness of Section 3(d) in preventing evergreening while simultaneously fostering

innovation and ensuring access to medicines.

RESEARCH OBJECTIVES

To examine the interpretation and application of Section 3(d) by Indian courts and patent authorities

To evaluate the impact of Section 3(d) on incremental innovation, R&D incentives, and investor confidence.

To conduct a comparative study of India's Section 3(d) with patentability standards in the United States and European Union.

To propose policy and procedural reforms that balance the goals of preventing evergreening, fostering innovation, and ensuring access to medicines.

RESEARCH METHODOLOGY

The current study follows a doctrinal and comparative research approach to law, with a primary focus on the interpretation and implication of Section 3(d) of the Indian Patents Act, 1970, with respect to evergreening and incremental innovation. The study is qualitative and analytical and relies both on primary and secondary sources. The study uses doctrinal analysis for the evaluation of the statutory and judicial views, comparative analysis involving the standards of the United States and the European Union for patents, and case study methods for the evaluation of the judicial rationale. Although the ambit is confined to pharmaceutical and ancillary innovations, the study critically analyzes unresolved issues under Section 3(d), and the endeavor would be to suggest the required reforms as a means of balancing innovation incentivization against public health concerns.

LEGAL REGULATIONS

INDIAN PATENT LAW AND EVERGREENING

Indian patent regime during the past five decades has been dynamic, bearing the mark of the pull between intellectual property protection and the public interest mandates[14]. The Patents

[14] N.S. GOPALAKRISHNAN & T.G. AGITHA, PRINCIPLES OF INTELLECTUAL PROPERTY 39–52 (2d ed. 2014).

Act, 1970, when first legislated, had been the result of the suggestion of the Ayyangar Committee Report (1959). The Committee had stressed the development of a patent regime which would encourage indigenous industrial development without allowing for monopolistic practice, especially when it came to the fields of drugs and chemicals[15]. India thus followed a pattern which limited product patents for drugs and chemicals and granted only process patents with limited durations.This system advanced public health goals by allowing domestic companies to manufacture less expensive generic copies of critical drugs using other than the usual processes, paving the way for India's strong generic drug industry. But with India's entry into the World Trade Organization (WTO) in 1995 and the resulting TRIPS obligations, India had to implement product patents for drugs and chemicals by 2005. The transition took place over three stages by means of amendments in 1999, 2002, and 2005, each successively harmonizing India's law with TRIPS commitments[16]. The biggest change was effected in 2005 when product patents for drugs were established. But as a mark of respect for India's immediate public health requirements, the legislature also ushered in Section 3(d), a subsection intended to thwart the practice of "evergreening" the extension of patent monopoly by incremental change of an existing drug.So the current Indian patent regime forms a fragile balance: compliance with TRIPS commitments and innovation stimulation, and the maintenance of access to cheaper drugs by virtue of provisions like Section 3(d), compulsory licenses, and pre-grant opposition.

SEC 3D OF PATENT ACT

Section 3(d), which provides that the mere isolation of a new form of a known substance which does not result in the invention of the known efficacy of a substance cannot be patented.

“The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance… shall not be considered an invention.”

Explanation of Section 3(d) provides for salts, esters, ethers, polymorphs, metabolites, isomers, and other derivatives which shall not continue as the same substance unless they differ

[15] JUSTICE N. RAJAGOPALA AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW 9–15 (Gov’t of India 1959).
[16] The Patents Act, No. 39 of 1970, §§ 5, 53 (India) (prior to amendment); Shamnad Basheer, India’s Tryst with TRIPS: The Patents (Amendment) Act, 2005, 1 INDIAN J.L. & TECH. 15, 18–22 (2005).

substantially from one another by means of efficacy [17].The intent of the legislature was specifically not to perpetuate evergreening[18]. Ever during the parliamentary debate for the 2005 amendment, legislators had contended that the drug majors were taking unfair advantage of the patent regime by asserting secondary patents for incremental changes and thus thwarting generic entry and keeping prices of drugs high[19]. Section 3(d) had accordingly been envisioned as a public health protection, specially adapted for India's socio-economic situation.

Remarkably enough, Section 3(d) does not prohibit patenting of incremental innovation as such but increases the threshold for them by insisting on a demonstration of heightened therapeutic efficacy. This balancing serves the purpose of encouraging true innovation while denying trivial variations for the mere extension of entitlement for monopoly.

TRIPS Agreement and India's Compliance

The TRIPS Agreement, which is governed by the WTO, establishes minimum requirements for the protection of intellectual property, such as patents. The TRIPS Articles 27-34 contain the substantive and procedure provisions for the law of patents. Article 27(1) requires the members to grant patents for any product or process, invention, when it is new, includes an inventive step, as well as capable of industrial use.

Yet TRIPS also confirms some flexibilities as a vehicle by which member states can tailor the laws for national interest. These include: Article 27(2) and 27(3): Makes exclusion from patentability possible for considerations of public order, morality, or for the protection of the human, animal, or plant body[20].

Article 31: allows for compulsory licence for listed purposes.

Doha Declaration on TRIPS and Public Health (2001): Enshrined the right of members to utilise the TRIPS flexibilities for facilitating access to medicines[21]. India's Section 3(d) adoption reveals an innovative interpretation of TRIPS flexibilities. In enhancing the standard

[17] The Patents Act, No. 39 of 1970, s.3(d), Explanation (India).
[18] JUSTICE N. RAJAGOPALA AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW 19–25 (Gov't of India 1959);
[19] Lok Sabha Debates, The Patents (Amendment) Bill, 2005, Mar. 23, 2005 (India)
[20] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27(2)–(3), Apr. 15, 1994, 1869 U.N.T.S. 299.
[21] Bryan Mercurio, TRIPS Flexibilities and Access to Medicines in Developing Countries, 8 NW. J. INT'L HUM. RTS. 1, 15–22 (2010).

of patentability for drugs, India pursued the harmonization of TRIPS compliance with the constitutional obligation towards the protection of public health by virtue of the Right to Life contained in Article 21. Section 3(d) was challenged by big drug multinational corporations as TRIPS-inconsistent, but the provision had not been challenged formally at the WTO[22]. The scholarly view widely confirms the validity of the provision by virtue of TRIPS flexibilities, particular after the Doha Declaration.

Landmark cases on sec 3D of the Patent Act

The success of Section 3(d) does not, however, solely rest with the textual content of the statute but with the meaning imparted by the judiciary and the executive. The Indian judiciary has been the single-most determinative institution for determining the reach of the provision and defining how the provision interplays with innovation and access to medicines. Three cases specifically Novartis AG v. Union of India, Roche v. Cipla, and successive oppositions and appeals have been the focal points for the meaning of Section 3(d).

Novartis AG v. Union of India (2013)

The pioneer case for Section 3(d) is Novartis AG v. Union of India (Supreme Court, 2013), which concerned the patenting for Imatinib Mesylate (Glivec), used for the treatment of chronic myeloid leukemia. Novartis had filed for the patent for the beta-crystalline form of Imatinib Mesylate, claiming novelty for the form by virtue of the improved physical properties and thus the improved bioavailability.

Application refused by the Patent Office under Section 3(d), as it also held the view that the beta-crystalline form came into the category of a "new form of a known substance" and did not prove increased therapeutic efficacy. After failing before the Madras High Court, the case came up before the Supreme Court.

The Supreme Court case primarily centered upon two arguments:

Meaning of the word "efficacy": The Court held that the term "efficacy" as used in Section 3(d) had to be tightly construed as therapeutic efficacy. Increased bioavailability, stability, or other physicochemical properties would not suffice unless they translated into demonstrated

[22] Frederick M. Abbott, The WTO Medicines Decision and Access to Medicines, 99 AM. J. INT'L L. 317, 325–30 (2005)

therapeutic advantages for the patient. Balancing innovation and public health: The Court acknowledged the reality that incremental innovations may yield tangible benefits to patients at times but reinforced the aspect that Section 3(d) was carefully drafted not to allow for trivial variation extending monopoly rights. The rejection of Novartis's patent was thereby upheld. The result was a historical one. It ratified India's capability to withstand pressures from multinational drug companies and put public health first. The ruling was acclaimed internationally as a triumph for access to medicines, keeping generic forms of Glivec affordable at a small fraction of the drug's patented cost. Nevertheless, opponents opine that the Court's limited view of efficacy may hamper real incremental innovations which benefit patient care indirectly.

Roche v. Cipla (2009–2015)

Another landmark dispute was F. Hoffmann-La Roche Ltd. v. Cipla Ltd., concerning Roche's patent for the lung cancer drug Erlotinib (Tarceva). Cipla launched a generic version, leading Roche to sue for infringement. Cipla, in turn, challenged the validity of Roche's patent, arguing that the invention was anticipated and lacked inventive step, and that Section 3(d) should apply to restrict patentability. Delhi High Court had originally supported Cipla, finding the patent wanting on the test of inventive step and Section 3(d). The Division Bench, in appeal, set aside partly, upholding the patent by Roche but observing also that the acts of Cipla were justified for the public interest. The importance of the case is the treatment accorded to public interest considerations. The Court specifically recognized that the Indian patent statute had to be construed from the perspective of access to medicines and thus entrenched public health into the jurisprudence of patents. Secondly, it demonstrated the ways in which Section 3(d), while not the only basis, operates along with other standards such as inventive step in limiting undeserving monopolies.

Other Pertinent Appeals and Oppositions

Some other cases have established the practice of Section 3(d):

Patent for Pfizer's Sutent (Sunitinib): Revoked pursuant to Section 3(d) due to failure to prove. GlaxoSmithKline's Valacyclovir case: Initially rejected under Section 3(d), later won on appeal after the presentation of additional data. Boehringer Ingelheim's Nevirapine syrup patent: Experienced pre-grant opposition based on Section 3(d), which illustrates the contribution of

civil society groups to the upholding of patent application[23]s. These cases follow a patterns where the Patent Office, India, routinely employs Section 3(d) and other thresholds (novelty, inventive step) for rejection of later-generation patents, but the outcome hinges on the evidentiary demonstration of efficacy. The evolving jurisprudence reflects the potential of Section 3(d) for curbing evergreening as well as the tension for the consistent application of an uncertain standard.The interpretation of Section 3(d) revolves around the undefined term "efficacy.[24]" The interpretation of the word eludes not just the court but even the examiners.

Practical Difficulties

Limited technology expertise for analyzing sophisticated clinical data. Lack of harmonised guidelines, i.e. discretionary and occasional arbitrary choices. Pressure from international stakeholders criticizing India's restrictive stance. For the innovators, time and money for the production of comparative clinical data prove expensive, especially for small companies. This deters rightful incremental innovations which could positively impact patients, though less spectacular ones.

Influence on Traditional Knowledge and AYUSH Innovations

While Section 3(d) was intended particularly to address pharmaceutical evergreening, its use has had influence on traditional knowledge systems and AYUSH (Ayurveda, Yoga, Unani, Siddha, and Homeopathy) innovations.

Community-Based and Herbal Innovations

Development of traditional medicines typically pertains to novel process or formulation of the known plant or natural source[25]. Patent applications under such category often invite Section 3(d) objections, as herbal derivatives fall under the category of "new forms of known substances" unless they are proven to be more efficacious[26] .For example, a study by Sharma & Ravikumar (2020) shows that a significant percentage of herbal patent filings face extended prosecution under Section 3(d) with negligible success rates. It offers both the challenge of

[23] Novartis AG v. Union of India, (2013) 6 S.C.C.
[24] Boehringer Ingelheim GmbH v. Controller of Patents, Pre-Grant Opposition Decision, Indian Patent Office (2008);
[25] WORLD INTELLECTUAL PROP. ORG., INTELLECTUAL PROPERTY AND TRADITIONAL MEDICINE 15–28 (2017).
[26] Rakesh Sharma & K. Ravikumar, Herbal Pharmaceutical Patent Protection:

generating clinical evidence for traditional medicine and the IPO's conservative attitude towards the grant of monopolies over community knowledge.

Case Studies

The Turmeric case (though prior to Section 3(d)) is one of opposition towards patenting known substances.Ayurvedic, Unani, Siddha and Homeopathy (AYUSH) products endorsed by the National Innovation Foundation have had mixed outcomes, with around 24% having been patented following intense examination[27] (Chauhana, 2022).The example suggests a conundrum: although Section 3(d) guards against misappropriation of indigenous knowledge, it might potentially discourage low-volume innovators from securing protection for legitimate improvements.

Observed Trend

Application of Section 3(d) within AYUSH scenarios reveals:

A disposition to reject claims unsupported by clinical evidence, even when they confirm historical usage and therapeutic effect. Prolonged prosecution, discouraging grass-roots innovation. Limited acknowledgment of traditional medicine's distinctive epistemologies, not directly correlatable with Western clinical paradigms.. This illustrates the need for adaptive guidelines for the evaluation of traditional knowledge-based patents.

Limitations and Criticism

Section 3(d) has been the focus of a lot of debate, eliciting opposing opinions from innovators, investors, public health experts, and academics. From an innovator's point of view, pharma companies maintain that the section makes patent outcomes unpredictable because of the uncertain interpretation of "efficacy[28].". They also fault the overly heavy evidentiary burden imposed on applicants, which could deter investment in marginal innovations such as better formulations or drug delivery systems, thus undermining India's position as a global hub of R&D relative to jurisdictions having better-defined standards. Investors also resonate these concerns by perceiving Section 3(d) to be a cog in a straitjacket intellectual property culture,

[27] National Innovation Foundation–India, Annual Report 2022, at 45–52; Rakesh Chauhan, Patent Protection and AYUSH Innovations in India, 14 J. INTELL. PROP. L. & PRAC. 201, 210–18 (2022).
[28] Bryan Mercurio, TRIPS, Patents, and Access to Medicines, 8 NW. J. INT'L HUM. RTS. 1, 18–25 (2010);

which erodes faith in returns and has, in certain instances, discouraged multinational companies from launching new drugs on time in the Indian market On the other hand, patients' associations and civil society organizations strongly favour the provision as a required public health intervention, and the Novartis decision was welcomed as a victory for access to affordable medicines by preventing evergreening and allowing India to maintain its status as the "pharmacy of the developing world[29]." Scholarship is the other dimension, which emphasizes the absence of consistent testing approaches that yield variable results, the narrow judicial definition of "efficacy" that risks excluding true innovations, and redundancy with the test of inventive step, raising skepticism about duplication and administrative efficiency. These perspectives together set out the delicate balance Section 3(d) attempts between incentivizing innovation and ensuring access to medicines, and reveal its practical and theoretical shortcomings as well.

Effect on Incremental Innovation

The Chilling Effect on Innovation

The uncertainty regarding the use of Section 3(d) has led to what has been broadly called a "chilling effect" on incremental innovation. Indian standards have long been attacked by pharmaceutical companies based on the argument that Indian standards do not distinguish between minor variations and improvement. Therefore, firms have a tendency to low-prioritize R&D for drug delivery systems, new forms, or dosage regimens for the Indian market. For example, liposomal drug delivery systems, which can potentially significantly reduce toxicity in cancer treatment, have struggled with granting patents under Section 3(d) due to problems with regard to demonstrable efficacy[30]. This is ironic: Section 3(d) seeks to facilitate access to low-cost medicines by discouraging mediocre patents, yet its restrictive use could limit patient access to quality innovative drugs for improving quality of life and adherence. Beyond Pharmaceuticals: Biotech, Agrochemicals, and Devices

Beyond Pharmaceuticals: Biotech, Agrochemicals, and Devices

The chilling effect is not limited to pharmaceuticals only. Section 3(d) has been increasingly

[29] U.S. Chamber of Commerce, International IP Index Report 2019, at 45–52; Prashant Reddy & Sumathi Chandrashekaran, CREATE, COPY, DISRUPT: INDIA'S INTELLECTUAL PROPERTY DILEMMAS 178–95 (2017).
[30] N.S. GOPALAKRISHNAN & T.G. AGITHA, PRINCIPLES OF INTELLECTUAL PROPERTY 189–230 (2d ed. 2014)

applied in the area of biotechnology and agrochemicals, where incremental innovation is equally critical. For instance, new formulations of pesticides with higher safety profiles or biopharmaceuticals with greater stability may be deprived of protection under the present interpretation of the law. Likewise, medical device technologies, especially incremental advances in delivery devices like insulin pens or inhalers, struggle to gain patent protection. These industries rely intensely on sequential increments, and the unpredictability of India's patent regime can dampen the incentive to launch such products in the Indian market.

Missed Opportunities and Policy Trade-Offs

Case reports highlight the actual-world impact of Section 3(d) and incremental innovation lost. Fixed-dose combinations for HIV treatment, that simplify regimens and increase compliance, have often been challenged under Section 3(d). Similarly, inhalation treatments for chronic illnesses such as asthma or COPD, re-configured for higher bioavailability, have been denied patents for failing to show sufficient therapeutic advantage. While these decisions align with the objective of the provision to ensure against evergreening, they also recognize loopholes in the reward for significant gains that would lead to improved patient care. At a grand scale, Section 3(d) is a policy trade-off between avoiding patent abuse extension and encouraging incremental innovation. Its defenders argue that it safeguards public health by ensuring access to life-saving drugs like Glivec at reasonable prices, while its opponents underscore the unintended effects: reduced R&D incentives, investor caution, and lost patient benefits in terms of improved drug designs or delivery system. Shortage of capacity to have consistent guidelines and vagueness in delineation of "enhanced efficacy" worsen inconsistency in patent examination, discouraging innovators even more[31]. Overall, although Section 3(d) has managed to prevent evergreening and enhance affordability, its excessive restrictive interpretation has the potential to harm India's innovation ecosystem[32]. In order to continue being capable of playing the twin role of protector of public health and facilitator of actual innovation, the provision must be well-balanced in order to tell the difference between paltry tweaks and actual advances. Without such reform, India risks unwittingly sacrificing its long-term capability for innovation but at the same time persisting in making a name for itself as the "pharmacy of the developing world.".

[31] Arti K. Rai, Interpretation of the Section 3(d) Standard in India, 12 NW. J. TECH. & INTELL. PROP. 376, 385–92 (2014).
[32] Bryan Mercurio, TRIPS, Patents, and Access to Medicines, 8 NW. J. INT'L HUM. RTS. 1, 18–25 (2010).

Contribution to India as "Pharmacy of the Developing World"

The capability of India to manufacture and export cheap medicines is a plank of India's international reputation[33]. African nations, Latin American nations, and Asian countries are dependent on Indian generics to tackle epidemics like HIV/AIDS, tuberculosis, and malaria. The World Health Organization (WHO), Global Fund, and other organizations have consistently procured Indian drugs for global health initiatives. Section 3(d) has assisted in cementing this function by preventing patents from becoming a legal hurdle to generic supply. For example, several fixed-dose combinations for HIV/AIDS were at first regarded as incremental innovation by international drug companies. Denials or oppositions based on Section 3(d) meant that Indian firms could produce these combinations without risking infringement of extended monopolies[34]. This regulatory framework has been hailed by international civil society organizations as a model of how to balance intellectual property and public health.

Challenges: Dependence on Generics Excess and Absence of Pro-Innovation Culture

While these have been some of the achievements, Section 3(d) has its own shortcomings. Section 3(d) is criticized on the basis that while it has been effective in stopping evergreening, it has unintentionally fostered an ambience that is too generics-dependent. The industry has a tendency to forego launching incremental innovations in India for fear of rejection under Section 3(d). This generates a paradox: patients enjoy cheap first-generation drugs, but miss out on better forms like more efficient delivery mechanisms, fewer side effects, or greater stability. For instance, asthma inhalation therapies, or HIV drugs reformulated to enhance adherence, have been rejected under Section 3(d) since enhanced bioavailability was not equated with improved therapeutic efficacy. Patients could therefore lose out on improvements that, although not revolutionary, can significantly enhance quality of life. The strict application of "efficacy" could discourage incremental innovation altogether. Investor confidence is also another area of concern. Some multinational corporations consider India's patent regime uncertain, deterring them from launching new technologies in the market in a timely manner. According to reports, drug launches in India are delayed due to uncertainty related to patent protection. It is true that this pessimism is perhaps overdone, but it does indicate the

[33] The Patents Act, No. 39 of 1970,
[34] Supra

requirement for more definitive guidelines regarding how "efficacy" has to be understood in practice. Additionally, excessive dependence on generics puts long-term sustainability into question. India's pharma sector has surpassed the art of reverse engineering and making cheaper versions of patented medicines but is weak in creating innovative drugs. Unless there are more incentives for R&D, India can fall back on being a manufacturing base but not an innovation hub for pharmaceuticals. Section 3(d) as it stands today could actually encourage this unless supported by policies that encourage true research while continuing to protect public health.

United States Patentability Standards

The United States patent regime, statutorized by Title 35 of the U.S. Code, is very liberal with regard to secondary pharmaceutical inventions and has effects on evergreening practices and incremental innovation. The three core provisions are §101 (Patentable Subject Matter), §102 (Novelty), and §103 (Non-obviousness). Section 101 grants patent protection for any new and useful process, machine, manufacture, or composition of matter, including their improvements. This is broad phrasing that permits pharmaceutical firms to patent new polymorphs, salts, esters, or formulations of known drugs. Section 102 applies a requirement of novelty such that the invention shall not have been divulged by prior art. Mere slight alterations of known substances will do the job given that the very same modification has never been divulged before. Section 103 is the crucial bulwark against trivial inventions such that patents shall not issue if the differences from prior art would have been obvious to a "person having ordinary skill in the art" (PHOSITA). Defining cases such as Graham v. John Deere Co. (1966) set out a formal analysis of non-obviousness that was later perfected by KSR International Co. v. Teleflex Inc. (2007), giving greater weight to an adventurous, common-sense approach. In practice, pharmaceutical companies use §103 by showing unforeseen outcomes like increased solubility, bioavailability, lower side effects, or greater stability to gain secondary patents. The U.S. regime permits widespread secondary patenting, building many layers of exclusivity, particularly under the Hatch–Waxman Act (1984). The system allows listing of patents in the "Orange Book," which invokes regulatory barriers against generics and promotes litigation to settle disputes. Iconic cases like Mylan v. Takeda exemplify that secondary patents have been used to extend exclusivity terms by often defying generic entry. Although the U.S. system strongly incentivizes incremental innovation while safeguarding R&D investments, criticism has also grown against allowing evergreening tactics that maintain high prices of drugs while defying public access to affordable drugs.

Furthermore, U.S. courts tend to view nominal physicochemical or formulation variation as patentable if supported by proved advantages irrespective of therapeutic efficiency. This contrasts with India's emphasis on actual clinical benefit. U.S. law thus favors innovation inducements and lucrative returns over prompt public health issues at the expense of creating an environment favorable for incremental pharmaceutical progress but that could deter early penetration of generics.

European Union Patentability Criteria

The EU patent regime, as delineated by the European Patent Convention (EPC) and governed by the European Patent Office (EPO), offers technically higher bar structure than the U.S., that is specifically for secondary patents[35]. Articles 52, 54, 56, and 57 of the EPC offer the essential patentability requirements: novelty, inventive step, and industrial application. Article 52 requires inventions to be new, involve an inventive step, and have industrial application. Article 54 sets out the idea of novelty analogously to U.S. s102. Article 56, which governs the requirement of inventive step, requires an invention not be obvious against prior art by a PHOSITA. Article 57 offers practical use of an invention.

EPO uses problem solution approach to create inventive step: closest prior art is established, technical problem is established, and obviousness of claimed invention is assessed. This formal approach obliges secondary inventions to prove tangible technical effect, such as improved stability, increased bioavailability, or pharmaceuticals that are simpler to produce, rather than theoretical advantages. In T 939/92 (AgrEvo/Triazoles), EPOTT refused widespread chemical protection with too faint technical effect, referring that structural variation alone if devoid of problem-solving capability is not patentable. Likewise, T 1329/04 (Johns Hopkins) ruled that technical advantages need to be realistic at grant rather than claimed ad hoc. Another EU system characteristic is grant of Supplementary Protection Certificates (SPCs) by Regulation (EC) No 469/2009 conferring market exclusivity extension for pharmaceuticals. Though SPCs may prolong effective patent term, they are governed by tight controls lest they are abused, as does happen in AstraZeneca v. Commission (2012), when principles of competition law stepped in to prevent anti-competitive exploitation of rights of patent[36]. The EU system thus strikes a balance between rewarding innovation on the one hand and public interest on the other

[35] Convention on the Grant of European Patents art. 1, Oct. 5, 1973, 1065 U.N.T.S. 199
[36] Duncan Matthews, Intellectual Property, Human Rights and Development 212–20 (2011).

by blending rigorous standards of testing with controls on competition. Unlike the U.S., the EU is not requising express therapeutic efficacy for secondary patents but will concede a demonstrable technical effect. Incremental inventions of such kind become patentable if they tackle an existing actual technical issue like chemical stability or optimization of the procedure. While such a system is narrower than that of the U.S., the EU concedes more secondary patents than India for which clinical efficacy is a requirement of Section 3(d) necessity. The EU thus achieves a middle balance: protecting innovation while keeping relatively trivial patents at bay but at the same time giving affordability and generic access lower consideration than that given by Indian law.

Contradictions and Comparative Comprehensions with India

India's Section 3(d) of the Patents Act, 1970, is a rare public health-focused approach that is quite different from U.S. and EU norms[37]. Section 3(d) mandates that the manufacture of a new form of a well-known substance by itself does not qualify for patenting unless the new substance exhibits enhanced therapeutic efficacy, expressly for preventing evergreening. In Novartis AG v. Union of India (2013), the Supreme Court has held that enhanced physicochemical characteristics such as stability, solubility, etc., are not enough to satisfy the criterion of efficacy by themselves. Similarly, in Roche v. Cipla (Delhi HC, 2008), courts reasserted Section 3(d) public health rationale by emphasizing affordability and generic competition.

Whereas U.S. patent law allows increment inventions with technical superiority even where there is no direct clinical benefit, and the EU finds technical effects enough there are a number of areas of conflict:

Non-human use inventions.

Threshold of Secondary Patents: Although the U.S. allows for subtle innovation if not obvious, the EU asks for technical effect but India asks for therapeutic efficacy, basically curbing patentability. Focus on Public Health: India achieves a better balance of medicine access within its patent system on its own, whereas U.S. and EU approaches prioritize more innovation

[37] The Patents Act, No. 39 of 1970, s. 3(d)

incentives, with market competition and litigation indirectly regulating access[38].

Innovation Impact: U.S. law heavily prefers incremental pharma R&D and patent portfolio creation. EU's system is somewhat restrictive but nonetheless prefers incremental innovation. India's strategy puts at a disadvantage some types of secondary patents, which would lower the expenditure on incremental innovation in the areas of pharmaceuticals, biotech, and medical devices. Regulatory Structure: U.S. reliance on litigation (Hatch–Waxman Act) and EU's monitoring of competition differs from India's statutory gatekeeping anticipating abusive patents at the examination level rather than at the post-grant level.

Third, these comparisons also include a central policy trade-off: innovation and access. The U.S. and EU strategies prefer widespread innovation incentives that accommodate late generic entry and high prices, while India prefers low prices and early generic competition at the expense of discouraging some marginal innovations[39]. These differences have practical consequences for drug firms, investors, and patients that influence R&D strategy of firms, market access strategy of firms, and public health outcomes.

CONCLUSION

Section 3(d) of the Indian Patents Act of 1970 is a rare public health oriented strategy that diverges significantly from U.S. and EU regimes. By requiring evidence of "enhanced therapeutic efficacy" for new formulations of established drugs, it has been able to stem evergreening, ensure generic competition, and ratify India's position as the "pharmacy of the developing world." Novartis AG v. Union of India (2013) and Roche v. Cipla (2008) reflect the court's commitment to safeguarding intellectual property rights from intrusion by access to medicines.

But Section 3(d)'s ambit extends beyond efficacy. Excessive strictness has unduly limited incremental innovation, particularly in the pharmaceutical, biotechnology, and medical devices space, where delivery system advancements of safety or stability might lack patent protection even if there's clear clinical utility. That's shaped investor opinions and discouraged market launch of incremental innovations. Further, there are lacunae in harmonizing traditional knowledge and AYUSH-based innovation with the patent regime. It is ironic to compare with

[38] Convention on the Grant of European Patents art. 56, Oct. 5, 1973, 1065 U.N.T.S. 199
[39] CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES 67–75 (2000);

the U.S. and EU as they permit secondary patents for technical advance or obviousness but India's policy of exclusion positions it against the international standards of innovation and raising doubts on its competitiveness.

Recommendations

Clarify Guidelines Beyond Efficacy where Patent examination standards should clearly include enhancements in stability, safety, and patient compliance, minimizing uncertainty for innovators.

Strengthen Patent Office Capacity. Regular training, standardized manuals, and open decision-making will eliminate inconsistencies and boost credibility.

Support Non-Patent Incentives R&D tax credits, public–private partnerships, and targeted grants can stimulate socially useful incremental innovation where patents are withheld.

Integrate AYUSH and Traditional Knowledge An exclusive evidentiary framework would prevent community based innovations from being relegated to the periphery under Section 3(d).

Supplement with Wider Policy Instruments Drug prices, purchasing, and insurance reforms must complement patent law to provide access, and not depend solely on limiting IP measures.

Learn from International Experience While maintaining its public health protections, India can borrow post-grant mechanisms (such as U.S. litigation or EU competition regulation) to minimize pressure on the examination phase.

Final Thoughts

Section 3(d) is still a trailblazing defense against evergreening, but its literalness may strangle incremental innovation and discourage investment. The challenge for India is to fine-tune its interpretation and place it within the context of an integrated innovation access ecosystem.

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