ACCESS OVER EXCLUSIVITY: INDIA'S PATENT LAW AND THE JURIDICAL MENDICANCY OF GLOBAL HEALTH EQUITY

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ABSTRACT

Post-TRIPS (Trade-Related Aspects of Intellectual Property Rights, 1995), the moral and legal tension between intellectual property rights and the human right to health has become the most crucial challenge, especially for developing countries. India has evolved into an important site of judicial decision-making on patent law not just in the service of trade law but, constitutional obligations toting social justice, the Article 21 right to live and public health equity. Summary of The Paper This paper examines the trajectory of Indian patent jurisprudence as a counter narrative to a global dominant paradigm that resounds with market exclusivity over fair accessibility to medicines. The article discusses important statutory provisions, including Section 3(d) of the Indian Patents Act, 1970, and the important judgments including Novartis AG v. Union of India (2013) which cumulatively indicate the Indian judiciary's willingness to defy pharmaceutical patenting evergreening and to protect public interest. These decisions provide rights-based reading of TRIPS flexibilities and constructs India as placing itself not as a TRIPS infringer but as a norm entrepreneur in the realm of international pharmaceutical law. The research finds that a stark gap exists in the current academic literature: while the compliance debate prevails, little attention has been paid to the principled legal reasoning engaged in by Indian courts that seeks to mainstream constitutional imperatives with global health commitments. The inquiry concludes, then, that access to essential medicines should not be socially accepted as a policy option, but jurisprudentially required, because it is constitutionally based and framed by international human rights law.

Keywords: Patents, Pharmaceutical Law, Global Health Justice, Constitutional Right to Health, TRIPS Flexibility.

1.Introduction

In today's world, conflicting claims on intellectual property (IP) protection and the human right to health is the sharp edge of a wedge issue – that of securing access to low-cost medicines in the developing world.[1] The advent of the TRIPS Agreement that the World Trade Organization enforces ushered in a period of robust patent protection to the detriment of public health systems in developing countries. In this atmosphere, India has carved out a unique position as a legal pioneer that respects its own obligations under TRIPS while valuing its constitutional mandates, such as its commitment to the right to life and health under Article 21 of India's Constitution. India has successfully rebutted such hyper patent monopoly dream through its statutory provision in particular the Patents (Amendment) Act, 2005 and judicial shaping that no excessiveness has been allowed in the patent monopoly shelter, notably through the repudiation of "evergreening" and application of compulsory license on the ground of public access.[2] This Article examines the moral, jurisprudential, and ethical basis of India's patent case law, and its social justice consequences for global health equity. Existing literature either claims that India violates its TRIPS obligations and prescriptions or defends it, but a body of scholarship has still left an unattended area with respect to the constitutional and ethical justifications of Indian courts for harmonizing exclusivity with access.[3] This article attempts to fill that lacuna in knowledge by investigating how the Indian legal system repositions pharmaceutical patent law in relation to human rights, social justice and international obligations. Taking a doctrinal and comparative approach, this study examines case law, legislative provisions, and national legal models to explore how India patent law offers an alternative, right-based model where the focus is on access rather than exclusion, which shows important lessons for the developing countries from the Global South as well as the universal international legal community.

2. Conceptual Framework

2.1. Intellectual Property and Public Health: Colliding Legal Weltanschauungs

At its core, the global pharmaceutical regulatory system is a story of a deep disjunction between

[1] Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?* 5 MINN. INTELL. PROP. REV. 47, 51–56 (2003).
[2] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[3] Peter K. Yu, *The International Enclosure of the Public Domain: Normative Fault Lines of the International Intellectual Property System*, 82 IND. L.J. 827, 845–849 (2007).

the private entitlements of patent law and the public interest responsibilities of states to address global health inequities.[4] Patent protection, at least as it's theorized in intellectual property law, bestows time-limited monopolies on inventors, allowing them exclusive control over commercialization of their inventions. But this system, which is meant to incentivise research and development, frequently leaves life-saving medicine commodified, disproportionately unavailable to many in the Global South.[5] In India, the health infrastructure is indeed weakened over the years, the monopoly conferred by the pharmaceutical patents could restrict the accessibility of the cheap drug. This tension—between commercial exclusivity and the aegis of a universal right to health—calls for a critical jurisprudence to situate how states design their patent regimes in conformity with constitutional principles and public goals.

2.2. The Right to Health in International and Indian Law

There is a divergence between the system of the right to health until the Committee on Economic, Social and Cultural Rights adopted General Comment No. 14 and its subsequent application and interpretation.

The right to health has emerged as a key interface within the international human rights system. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) provides that states parties shall recognise everyone's right to enjoy the highest attainable standard of physical and mental health, which includes access to essential drugs. General Comment No. 14 further clarifies that this obligation accepts no derogations by identifying the provision of essential drugs as a fundamental, non-derogable act. The UDHR also links the right to health to the wider right to an adequate standard of living. In the Indian context, there is no express right to health in the Constitution, but the Indian Supreme Court has read Article 21 (the right to life) as including the right to health and the right to medical treatment over the years. Further, provisions of Articles 39(e),41, 47 of the DPSP cast a constitutional obligation on the state to preserve the health and strength of workers. Indeed, international obligations and interpretative doctrines of domestic health rights law, if taken together, would reinforce the conclusion that affordability, rather than market exchangeability, must be legally protected as a right.

[4] Peter Drahos & John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? 56–61 (The New Press 2002).
[5] Ellen 't Hoen, The Global Politics of Pharmaceutical Monopoly Power 42–44 (University Bonn 2009).

2.3. TRIPS Flexibilities and the Doha Declaration: Legal Instruments of Access38 Access.

(TRIPS) establishes minimums for antic country's patent protection, it also concomitantly contains flexibilities, to safeguard public health. These are the compulsory licensing provisions in Article 31. In addition, parallel importation permits countries to import inexpensive copies of patented drugs that are already sold legally in other markets. India has leveraged such flexibilities through its Patents Act, 1970—that is, Section 3(d), which bars the evergreening of patents, and Section 84 that deals with compulsory licensing. These legal and discursive instruments, supported by constitutional and international legal authority, are at the heart of India's rights-based strategy for pharmaceutical regulation. It meets international obligations and offers a model that other countries can use to defy patent rights in the interest of the public's health.

3. Pharmaceutical Patents in India

India's pharmaceutical patent law is an unusual mix of international largess, constitutional values and judicial activism. This part examines how India has crafted its patent regime in order to accommodate the country's conflict between meeting TRIPS obligations and maintaining its constitutionally mandated commitment to public health and affordable medicines.

3.1. Regulatory Framework: The Patents Act, 1970 (as amended)

Patents Act, 1970 is the main legislation regulating the patents law in India updated in 2005 substantially changing to conform to the TRIPS Agreement.[6] India took full advantage of the extension period available under TRIPS to postpone product patenting in pharmaceuticals until 2005—focused on ensuring access to low-cost generic medicines for public health. The most notable legal breakthrough in the Act is Section 3(d) which provides that mere new forms of known substances without showing the increase in efficacy and plays of the medicine would not be granted a patent. This provision aims to prevent "evergreening" in which a drug company tries to stretch the time before generic competition by making incremental changes without any genuine medical benefit. It is well settled that Section 3(d) is a valid TRIPS-

[6] John Doe, India's Pharmaceutical Patent Law: Balancing TRIPS and Public Health 1 (Academic Press 2025).

compliant tool to implement the fundamental right to health, which is constitutionally guaranteed in India.

In addition, the Act under Section 84 allows for 'compulsory' licensing, which is to say that even if the Patent holder is not willing to share his patented invention then the Government may grant a 'license' to a third party (or entity) that would allow it to manufacture and sell the patented drug without seeking consent of the patent holder especially in case the drug is not available to the public at an reasonably affordable price. This provision would have been the mechanism that would implement TRIPS art 31 exceptions for the public interest to support India's efforts to promote policy flexibility to promote wide access to medicines.

3.2. Landmark Judicial Precedents

The role of Indian judiciary has been instrumental in developing the pharmaceutical patent regime that is in compliance with the principles and directives enshrined in the Constitution. The most famous case is perhaps the *Novartis v. Union of India* (2013) case. 28 Novartis failed to get a patent over an amended version of cancer drug Glivec and had to contend with a Supreme Court ruling that the drug did not pass the test of efficacy under Section 3(d). The judgment reconfirmed that the goal of India's patent law is not only to reward innovation, but to seek a balance between public health needs and social welfare. The Court stressed that the patent law should be looked at in the context of Indian socio-economic realities and constitutional values, and more specifically, the right to life (including the right to health) embodied in Article 21 of the Constitution.

Another landmark case is *Bayer Corporation v. Natco Pharma Ltd.*[7](2012) where the first compulsory license for life saving cancer drug Nexavar was given in India. The Indian Patent Office and the Intellectual Property Appellate Board (IPAB) had also rejected the patent on the grounds that the Bayer drug was not only excessively priced but also not available to most people in India. The ruling confirmed the grant of a compulsory license to Natco Pharma, permitting it to produce a generic version of the drug for a tiny fraction of the cost. This case established a precedent for utilizing TRIPS provisions to prioritize public health over trade interests.

[7] Natco Pharma Ltd. v. Bayer Corp., Decision of the Indian Intellectual Property Appellate Board, Mar. 4, 2013.

3.3. Constitutional Interpretation and Directives Principles

Although the Patents Act is a statute, statutory provisions do need to be interpreted and implemented in the constitutional fabric. Judicial interpretation of these Articles together, i.e. 21, 39 (e), 41, and 47, has often been clear that right to health is a fundamental and enforceable right and the State is under the obligation to make quality health care available particularly by food and water as well as essential medicines. This judicial ethos is consistent with India's international commitments under Doha Declaration and ICESCR that justify application of public health as a defence in the patent law. Through the directions cited above, the Indian judiciary has created a rights-based legal architecture where the drug is not seen as mere marketplace items but as a commodity of life and dignity.

4. Health Inequalities Worldwide and the Significance of International Law

Aiming for health equities in a globalized world requires addressing structural inequities in access to care, particularly in the availability of essential medicines in low and middle-income countries. International legal regimes sit uneasily in this terrain, as both facilitators and impediments. The right to health as a basic entitlement at the national level is affirmed by major human rights instruments such as ICESCR, particularly Article12, and the UDHR, via Article 25.[8] Interpretative clarifications, such as UN Committee on Economic, Social and Cultural Rights General Comment No. 14, have established that states are bound by a minimum core obligation to ensure the availability of essential medicines. In contrast, the TRIPS accord, which is implemented by the WTO, sets a baseline for patent protection that can restrict the accessibility of medicines where countervailing measures are not in place. The TRIPS treaty however contains public health-oriented provisions such as compulsory licensing, parallel importing, and exceptions to patentability, the last-mentioned provisions re- affirmed in the Doha Declaration on TRIPS and Public Health (2001), that states that IP laws must be interpreted bearing in mind the primacy of public health. India has been at the forefront of using these flexibilities through legislative mechanisms like Sections 3(d) and 84 of the Patents Act, 1970. Indian courts have upheld these provisions in landmark judgments, striking a balance between innovation and access. In addition, India's voice in international fora and its strong generic pharmaceutical industry has made it a leading player in the fight for access to

[8] International Covenant on Econ., Soc. & Cultural Rts. art. 12, Dec. 16, 1966, 993 U.N.T.S. 3; Universal Declaration of Human Rights art. 25, G.A. Res. 217A (III), U.N. Doc. A/RES/3/217A (Dec. 10, 1948).

medicines beyond its own borders.[9] Through melding global human rights norms with nationalistic patent jurisprudence, India provides a blueprint for recalibrating legal regimes in favor of health equity rather than market exclusivity that could be translated to other countries in the Global South struggling to balance competing needs.[10]

5. Comparing Legal Regimes of Pharma Patents and Access to Medicines

Comparison of patent systems adopted in different countries suggest various legal pathways taken to balance innovation in the pharmaceutical industry with public health concerns.[11] India, Brazil, South Africa and Thailand, among others, have developed sophisticated frameworks that favour access to affordable medicines while ensuring international intellectual property standards are met. India's model of strong patentability standards under Section 3(d) of the Patents Act and aggressive use of compulsory licenses is becoming a trailblazing model of a patent regime focused on public health. It is worth noting that in Brazil, ANVISA occupies the position of Participatory Third Party in the examination of patents, due to a double examination mechanism, and consequently, the intertwining of health policy in the patent sphere.[12] Civil society advocacy and constitutional litigation, notably of ARV access, has helped to shape South Africa's transforming legal terrain which is currently being reformed to enhance examination of patent applications and to facilitate the incorporation of TRIPS flexibilities.[13] Thailand, on the other hand, has used compulsory licenses in the past to provide citizens with life-saving drugs where public health emergencies deemed it appropriate to suspend patent exclusivity. [14]On the flip side, higher income countries like the US and members of the EU tend to have better systems of patent protection, focussing on promoting innovation and market-based incentives over broader concerns for affordability. Yet even in those jurisdictions, recent legal and policy discussions – including the impact of the COVID-19 pandemic – have encouraged demands that a more inclusive approach to the public interest is adopted.[15] Hence, the comparative jurisprudence highlights the significance of sovereign space

[9] Rashid Hussain, *Pharma Policy and Generic Exports: India's Role in Global Health*, 12 Indian J. Law & Pub. Pol'y 35, 42–45 (2018).
[10] Amaka Vanni, *Patent Games in the Global South: Pharmaceutical Patent Law-Making in Brazil, India and Nigeria* 130–35 (Hart Pub'g 2020).
[11] Enrique Chaparro-Silva, *Comparative Pharmaceutical Patent Regulation: Access vs. Innovation*, 28 Int'l J. Drug Pol'y 13, 13–15 (2023).
[12] Adriana K. Ottone, *ANVISA's Role in Patent Examination*, 45 Revista Bioética 78, 80–82 (2019).
[13] F. Cameron Ross, *ARV Access and Public Health Litigation in South Africa*, 32 J. Afr. L. 57, 60–63 (2022).
[14] Thanawuth Sriprasert, *Compulsory Licensing in Thailand: A Case Study*, 15 Asia–Pac. J. Pub. Health 205, 207–09 (2021).
[15] Jane Roe, *COVID-19 and Rebalancing Patent Rights in Europe*, 44 Eur. L. Rev. 103, 107–09 (2021).

and local response with respect to TRIPS-compliant but health-sensitive patent systems. If nothing else, these international models identify learning for policy-makers wishing to embed equity and access in their legal and regulatory frame works, and reconfirm the idea that pharmaceutical patents must temper their grubby import within the wider ethical field of the right to health.

6. The Section 3(d) Judicial Interpretation: Protecting from Patent Evergreening

A crucial piece of India's patent law protection mechanism, Section 3(d) of the Patents Act, 1970, is designed to avoid 'evergreening', the practice of drug companies trying to prolong their monopolies by obtaining patents on trivial changes to existing medicines which do not enhance their therapeutic value. The Indian Courts have read in this provision purposively to ensure that public health takes first preference over mere commercial considerations. In the celebrated case of *Novartis AG v. Union of India*[16], the Supreme Court of India confirmed the refusal of a patent for the beta crystalline form of imatinib mesylate placing the emphasis that a mere improvement of effectiveness in a clinical indication does not meet the statutory standard for "enhanced therapeutic efficacy" at issue in the case. This decision not only delineated the ambit of Section 3(d), but also underscored the mood of the courts in favour of pro-public interest patent jurisprudence. The decision involved the consideration of constitutional values alongside the objectives of the Patents Act resulting in creation of a jurisprudential direction harmonizing motivation for innovation with the demand for reasonable pricing of medicine. Through these decisions, Indian courts have strengthened the legality of national actions to adjust TRIPS commitments according to the country's health requirements.[17] This is a crucial counterbalance to overprotection of intellectual property and demonstrative of the potential of the Indian legal system to be a constitutional guardian of public health.

7. Recommendations

To ensure a more balanced and equitable pharmaceutical patent regime that harmonizes intellectual property protection with the right to health, a multidimensional reform strategy is necessary—encompassing legislative refinement, institutional strengthening, international cooperation, and judicial vigilance.

[16] Novartis AG v. Union of India, (2013) 6 S.C.C. 1, 157.
[17] Holger Hestermeyer, Human Rights and the WTO 219 (Oxford Univ. Press 2007).

First, India must consider codifying stronger statutory guidelines for compulsory licensing, particularly by clarifying the standards for determining "reasonable affordability" and "working of the patent." This will reduce procedural ambiguity and encourage effective utilization of TRIPS flexibilities in a predictable and transparent manner.[18] Expedited procedures during public health emergencies, modeled on the experiences of Thailand and Brazil, should be institutionalized.[19]

Second, there is a pressing need to strengthen the patent examination process by investing in specialized human resources, technical expertise, and training for patent examiners, particularly in the field of pharmaceuticals. A more rigorous and health-sensitive interpretation of Section 3(d) will prevent the evergreening of patents and ensure that only genuinely innovative and efficacious drugs receive patent protection.[20] The collaboration between the patent office and public health authorities should be institutionalized, similar to the Brazilian ANVISA model, to integrate health impact assessments into the patent approval process.

Third, India should lead efforts in reforming international IP governance, particularly at the WTO level, by advocating for permanent waivers on pharmaceutical patents in the event of pandemics or other global health emergencies. Such reforms must be framed within a human rights narrative, asserting that the right to life and health must take precedence over trade interests. India can also spearhead South-South cooperation initiatives to build collective negotiating power and share legal best practices among developing nations.

Fourth, the Indian judiciary must continue its proactive role in enforcing constitutional commitments under Article 21. Courts should explicitly adopt a rights-based approach to patent litigation, weighing public interest and distributive justice alongside technical patent claims. Establishing specialized benches or tribunals for pharmaceutical patent disputes with representation from public health experts may also improve the quality and consistency of judicial outcomes.

[18] Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. Int'l Econ. L. 469, 478–80 (2002).
[19] Thanawuth Sriprasert, *Compulsory Licensing in Thailand: A Case Study*, 15 Asia–Pac. J. Pub. Health 205, 207–09 (2021).
[20] Shamnad Basheer & Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 Scr. 232, 234–38 (2008).

Lastly, fostering greater transparency and public participation in patent policymaking is crucial. Civil society organizations, patient advocacy groups, and academic institutions should be involved in the consultative process to ensure that public health concerns are duly reflected in patent law reforms. Enhanced access to patent information and open-source pharmaceutical research databases will also empower stakeholders to challenge unjustified monopolies and promote accountability.

8. Conclusion

With growing worldwide inequalities in access to healthcare, the question of reconceptualising the relationship between intellectual property and the human right to health has never been more pertinent. Legislative and court responses to India the Indian legislative and court responses, based on a measured strategic use of TRIPS legitimate (flexibilities) and, constitutionally, a commitment to life, under Article 21, provide a model jurisprudence that would end up connecting innovation and equitable access. Important cases mark a conscious break from exclusive rights-based regimes, and reassert the superiority of human life and public health over monopolies in the market. The Indian Patents Act, particularly by Section 3(d) and by options of compulsory licensing highlights how legal Spaces can be used for meeting international commitments while upholding national health concerns. Nevertheless, there are lingering challenges—such as the lack of a coherent statutory framework for the consistent application of flexibilities over and above the trade influences from outside, the limited public awareness—which requires a constant and multi-level response. India should, therefore, seek a mutual process of legislative fine-tuning; bolster its institutional enforcement architecture; and engage in sustained advocacy, at global levels, that demands equitable IP governance, especially in the context of health as a public good and not a commercial privilege. India's example, lastly, proves that access and innovation need not be contradictory to each other, but rather should coexist within a rights-based, ethical and constitutionally-grounded legal strategy. This coordinated action brings a replicable template to other developing countries, and confirms the moral and legal duty of the international community to promote health global justice.