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PATENTS OR PATIENTS: REBALANCING PHARMACEUTICAL INTELLECTUAL PROPERTY AND THE RIGHT TO HEALTH IN INDIA

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Abstract

India occupies a paradoxical position in the global pharmaceutical landscape. Dubbed the "pharmacy of the developing world," it supplies generic medicines to millions across Africa, Asia, and Latin America. Yet this very capacity rests on a patent regime that, until 2005, recognised only process patents, not product patents, in pharmaceuticals. The World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights compelled India to introduce product patent protection for pharmaceuticals, fundamentally altering the legal architecture that had enabled its generic industry to flourish. The resulting tension between patent rights and the right to health is not merely economic; it is constitutional. India's Constitution guarantees the right to life under Article 21, which the Supreme Court has interpreted to encompass the right to health and access to essential medicines. This article examines the doctrinal, statutory, and constitutional tensions between pharmaceutical intellectual property and the right to health in India. It traces the evolution of India's patent regime from the Patents Act of 1970 through the TRIPS-mandated amendments of 2005, analyses the judicial construction of Section 3(d) as a bulwark against evergreening, evaluates the operation of compulsory licensing under Section 84, and interrogates the constitutional foundations of the right to health. Drawing on comparative developments in South Africa, Brazil, and Thailand, and grounding its analysis in international law including the Doha Declaration on TRIPS and Public Health, the International Covenant on Economic, Social and Cultural Rights, and the General Comment No. 14 of the Committee on Economic, Social and Cultural Rights the article proposes a framework for rebalancing pharmaceutical intellectual property and the right to health that is rooted in India's constitutional commitments, faithful to its TRIPS obligations, and responsive to the realities of a country where millions lack access to essential medicines.

ISSN: 2582-6433

1. Introduction: The Patent-Health Paradox

The relationship between pharmaceutical patents and public health is among the most contentious fault lines in contemporary international law. On one side stands the argument that patent protection incentivises innovation: without the temporary monopoly conferred by a patent, pharmaceutical companies would lack the financial incentive to invest billions in research and development of new drugs.[1] On the other stands the reality that patent monopolies raise drug prices beyond the reach of the world's poor, denying access to life-saving medicines for diseases ranging from HIV/AIDS to cancer to hepatitis C.[2]

India sits at the epicentre of this conflict. For thirty-five years, from 1970 to 2005, India's patent law recognised only process patents in pharmaceuticals, not product patents.[3] This meant that while a particular method of manufacturing a drug could be patented, the drug itself could not. Indian generic manufacturers could lawfully produce patented drugs using alternative processes, resulting in some of the lowest drug prices in the world.[4] India became the primary supplier of affordable generic antiretrovirals for HIV treatment across the developing world, a role that earned it the title "pharmacy of the developing world."[5]

The World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights, which India ratified as a condition of WTO membership, required India to introduce product patent protection for pharmaceutical inventions by 2005.[6] The Patents (Amendment) Act of 2005 extended product patent protection to pharmaceuticals for the first time since independence, subjecting India's generic industry and the millions who depend on it to a legal regime that prioritises exclusive rights over access.

This article examines whether and how India's legal framework can reconcile patent protection with the right to health. It proceeds in five parts. Part II traces the historical evolution of India's

[1] William M. Landes & Richard A. Posner, *The Economic Structure of Intellectual Property Law* 294–311 (Harvard Univ. Press 2003).
[2] Joint United Nations Programme on HIV/AIDS (UNAIDS), *Access to Medicines: The Global Patent System and the Right to Health* 12–18 (2007).
[3] *The Patents Act, 1970*, No. 39, Acts of Parliament, 1970, § 5 (India).
[4]) K. Balasubramaniam, *Access to Medicines: Patents, Prices and Public Policy—Consumer Perspectives*, in *Trading in Knowledge* 223–40 (Christophe Bellmann et al. eds., 2003)..
[5] Médecins Sans Frontières, *Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries* 6 (2003
[6] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], art. 65(4).

ISSN: 2582-6433

pharmaceutical patent regime. Part III analyses the key provisions of the post-TRIPS patent framework, particularly Section 3(d) and the provisions on compulsory licensing. Part IV examines the constitutional foundations of the right to health and the judicial construction of access to medicines as a fundamental right. Part V evaluates the international legal framework, including TRIPS flexibilities and the Doha Declaration. Part VI proposes a framework for rebalancing pharmaceutical intellectual property and the right to health in India.

2. From the Patents Act of 1970 to TRIPS: A Historical Overview

2.1. The Colonial Inheritance and the Patents Act of 1970

India's first patent law was the Patents and Designs Act of 1911, enacted during British colonial rule.[7] The 1911 Act provided product patent protection for pharmaceuticals, a regime that primarily served the interests of foreign pharmaceutical companies. By the time of independence in 1947, foreign companies controlled over 80% of the Indian pharmaceutical market, and drug prices were among the highest in the world.[8]

Two committees, the Tek Chand Committee in 1950 and the Ayyangar Committee in 1959, recommended fundamental reform of the patent system to serve India's developmental needs.[9] Justice N. Rajagopal Ayyangar's report was particularly influential. It observed that product patents in pharmaceuticals had enabled foreign companies to monopolise the Indian market, suppress domestic manufacturing, and charge extortionate prices.[10] The Ayyangar Committee recommended the abolition of product patents in pharmaceuticals and the introduction of short-duration process patents.

Parliament enacted these recommendations in the Patents Act of 1970. Section 5 of the Act excluded claims for substances intended for use, or capable of being used, as food or medicine, limiting patent protection in these sectors to the process of manufacture.[11] The term of process patents was set at seven years from the date of filing or five years from the date of sealing, whichever was shorter, far shorter than the fourteen-year term available for other inventions.[12] The impact was transformative. Between 1970 and 2005, India's generic pharmaceutical

[7] *The Patents and Designs Act, 1911*, No. 2, Acts of the Governor General in Council, 1911 (India).
[8] N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law* ¶¶ 50–62 (1959) (India).
[9]] *Id.* ¶¶ 89–107.
[10] *Id.* ¶¶ 112–28.
[11] T*he Patents Act, 1970*, No. 39, Acts of Parliament, 1970, § 5 (India).
[12] *Id.* § 53(2).

ISSN: 2582-6433

industry grew from near-nonexistence to the third-largest in the world by volume.[13] Drug prices fell dramatically, and Indian manufacturers began supplying affordable generics to developing countries worldwide.[14] The HIV/AIDS crisis of the early 2000s underscored India's role: when first-line antiretroviral therapy cost over 10000 per patient year under patent and the product brand-name drugs, Indian generic manufacturers offered under the same regime.[15]

B. TRIPS and the Transition Period

The Uruguay Round of trade negotiations, concluded in 1994, established the WTO and imposed uniform intellectual property standards on all member states through the TRIPS Agreement.[16] Article 27(1) of TRIPS requires that patents be available for any invention, whether a product or a process, in all fields of technology, without discrimination.[17] Article 70(8) required developing countries like India that did not provide product patent protection for pharmaceuticals to establish a "mailbox" mechanism to receive patent applications from 1995 onward, to be examined once product patent protection came into effect.[18] Article 70(9) required the grant of exclusive marketing rights during the transition period.[19]

India initially resisted. It failed to amend its patent law by the TRIPS deadline, prompting the United States to file a complaint with the WTO Dispute Settlement Body. In India Patent Protection for Pharmaceutical and Agricultural Chemical Products, the Appellate Body held that India had violated its obligations under Articles 70(8) and 70(9) by failing to establish a mailbox system and exclusive marketing rights.[20] India complied through the Patents (Amendment) Act of 1999, which introduced the mailbox mechanism and exclusive marketing rights, and the Patents (Amendment) Act of 2002, which further aligned Indian law with TRIPS.[21]

The Patents (Amendment) Act of 2005 completed the transition. Section 5 of the 1970 Act

[13] Anand G. Bhatt, *Indian Pharmaceutical Industry in the New Patent Regime*, 13 *Indian J. Med. Ethics* 148 (2016).
[14] Yusuf K. Hamied, *The New Indian Patent Act: A Pharma Revolution*, 11 *Express Pharma Pulse* 18 (2005).
[15] Médecins Sans Frontières, *supra* note 5, at 8–10
[16] Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154.
[17] TRIPS Agreement, *supra* note 6, art. 27(1).
[18] *Id.* art. 70(8).
[19] *Id.* art. 70(9).
[20] Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997).
[21] *The Patents (Amendment) Act, 1999*, No. 17, Acts of Parliament, 1999 (India); *The Patents (Amendment) Act, 2002*, No. 38, Acts of Parliament, 2002 (India).

ISSN: 2582-6433

which had excluded product patents in pharmaceuticals was deleted.[22] Product patent protection for pharmaceuticals became available in India for the first time since 1970, with a patent term of twenty years from the date of filing, as required by Article 33 of TRIPS.[23]

3. The Post-TRIPS Framework: Section 3(d), Compulsory Licensing, and Judicial Interpretation

3.1. Section 3(d): The Anti-Evergreening Provision

The most distinctive feature of India's post-TRIPS patent regime is Section 3(d) of the Patents Act, as amended in 2005. Section 3(d) provides that a mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance, is not a patentable invention.[24] The Explanation to Section 3(d) states that for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers, isomer mixtures, complexes, combinations, and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.[25]

Section 3(d) was enacted to address the practice of "evergreening", the strategy by which pharmaceutical companies extend patent protection beyond the twenty-year term by obtaining new patents on minor modifications of existing drugs, such as new polymorphic forms, salt forms, or dosing regimens, that offer no significant therapeutic advance.[26] Evergreening is a well-documented phenomenon in the pharmaceutical industry. A study of new drug approvals in the United States found that between 1989 and 2000, only 15% of the 1,035 new drug applications approved by the FDA involved new molecular entities; the remainder were modifications of existing drugs.[27]

The constitutional and moral urgency of Section 3(d) is plain: in a country where over 60% of health expenditure is out-of-pocket[28] and where an estimated 50 million people are pushed into

[22] *The Patents (Amendment) Act, 2005*, No. 15, Acts of Parliament, 2005, § 4 (India) (deleting § 5 of the 1970 Act).
[23] TRIPS Agreement, *supra* note 6, art. 3
[24] *The Patents Act, 1970*, § 3(d) (as amended 2005) (India).
[25] *Id.* Explanation to § 3(d).
[26] Tahir Amin & Priti Radhika, *Evergreening: The Indian Experience*, 19 *J. World Intellect. Prop.* 275 (2016
[27] National Institute for Health Care Management Foundation, *Changing Patterns of Pharmaceutical Innovation* 6 (2002).
[28] World Health Organization, *India: Health System Review* 62 (2022).

ISSN: 2582-6433

poverty each year by healthcare costs,[29] the grant of patents on marginal modifications of known drug inflating prices and delaying generic competition is not merely an intellectual property question; it is a question of life and death.

3.2. Novartis AG v. Union of India: The Judicial Construction of Section 3(d)

The seminal judicial interpretation of Section 3(d) was laid down in *Novartis AG v. Union of India*.[30] Novartis had obtained a patent for imatinib mesylate in its beta-crystalline form, marketed as Glivec (Gleevec), a breakthrough drug for chronic myeloid leukaemia. The Indian patent office rejected the patent under Section 3(d), holding that the beta-crystalline form of imatinib mesylate was merely a new form of a known substance that did not enhance therapeutic efficacy.[31] The Intellectual Property Appellate Board (IPAB) upheld the rejection. Novartis challenged the decision before the Supreme Court.

The Supreme Court's judgment, delivered on April 1, 2013, was a landmark. The Court held that Section 3(d) was constitutionally valid and TRIPS-compliant, rejecting Novartis's challenge that the provision violated the non-discrimination requirement of Article 27(1) of TRIPS.[32] The Court interpreted "efficacy" in Section 3(d) to mean therapeutic efficacy, the ability of the substance to produce a beneficial effect on the body in the treatment of a disease.[33] Increased bioavailability, the extent to which a drug is absorbed by the body, did not per se constitute enhanced therapeutic efficacy; what mattered was whether the increased bioavailability translated into a significant improvement in the therapeutic outcome for the patient.[34]

The Court further held that Section 3(d) did not set a higher standard of inventiveness than what TRIPS required; rather, it addressed a specific form of evergreening that India, given its public health context, was entitled to guard against.[35] The judgment was widely celebrated by public health advocates and criticised by the pharmaceutical industry. The Pharmaceutical Research and Manufacturers of America (PhRMA) described the decision as a blow to

[29] S. Selvaraj & A.K. Karan, *Catastrophic Health Expenditure and Poverty in India*, 46 *Economic & Political Weekly* 101 (2011).
[30] *Novartis AG v. Union of India*, (2013) 6 SCC 1.
[31] *Id.* ¶ 8.
[32] *Id.* ¶¶ 108–18.
[33] *Id.* ¶ 104.
[34] *d.* ¶¶ 103–06.
[35] *Id.* ¶¶ 119–28.

ISSN: 2582-6433

innovation; Médecins Sans Frontières hailed it as a victory for access to medicines.[36]

3.3. Compulsory Licensing under Section 84

The Patents Act provides for compulsory licensing under Section 84, which allows any person to apply for a compulsory license three years after the date of grant of a patent on any of the following grounds: (i) that the reasonable requirements of the public with respect to the patented invention have not been satisfied; (ii) that the patented invention is not available to the public at a reasonably affordable price; or (iii) that the patented invention is not worked in the territory of India to meet the reasonable requirements of the public.[37]

The first and to date the only compulsory license granted in India was in Bayer Corp. v. Natco Pharma Ltd.[38] Bayer held a patent for sorafenib tosylate, marketed as Nexavar, a drug for advanced kidney and liver cancer. The drug was priced at approximately ₹2,80,000 per month of treatment, far beyond the means of virtually any Indian patient.[39] Natco Pharma applied for a compulsory license, offering to sell the drug at ₹8,800 per month and to pay Bayer a royalty of 7% of net sales.

The Controller of Patents granted the compulsory license on all three grounds under Section 84.[40] The IPAB upheld the grant, and the matter ultimately reached the Supreme Court, which declined to interfere with the concurrent findings of the Controller and the IPAB.[41] The *Natco* decision established several important principles: that "reasonable requirements of the public" is not limited to the demand that the patentee can satisfy, but encompasses the total demand; that a price is not "reasonably affordable" merely because the patentee offers a patient assistance programme; and that a patent is not "worked" in India merely because the product is imported local manufacture may be required.[42]

3.4. The Boundaries of Compulsory Licensing: Section 107A and the Bolar Exemption

Section 107A of the Patents Act, inserted by the 2002 Amendment, provides a Bolar-style

[36] Médecins Sans Frontières, *India: The Pharmacy of the Developing World*, Press Release (Apr. 1, 2013); Pharmaceutical Research and Manufacturers of America, *Special 301 Submission* 55 (2013).
[37] *The Patents Act, 1970*, § 84(1) (as amended 2005) (India).
[38] *Bayer Corp. v. Natco Pharma Ltd.*, Order No. 45/2012 (Controller of Patents, Mar. 9, 2012).
[39] *Id.* ¶ 22.
[40] *Id.* ¶¶ 47–62.
[41] *Bayer Corp. v. Natco Pharma Ltd.*, FAO(OS) No. 86/2013 (IPAB 2013); *Bayer Corp. v. Natco Pharma Ltd.*, SLP(C) No. 14398/2013 (S.C. India, dismissed May 2014).
[42] *Bayer Corp.*, Order No. 45/2012, ¶¶ 48–56.

ISSN: 2582-6433

exemption: it is not patent infringement to make, use, construct, or sell a patented invention for purposes reasonably related to the development and submission of information required under any law in India or any other country that regulates the manufacture, sale, or use of any drug or medicine.[43] This provision enables generic manufacturers to conduct the necessary bioequivalence studies and regulatory filings during the patent term, so they can enter the market immediately upon patent expiry.

The Bolar exemption is a TRIPS-consistent flexibility recognised in several jurisdictions.[44] In the United States, it was judicially created in Roche Products, Inc. v. Bolar Pharmaceutical Co.,[45] and subsequently codified in the Hatch-Waxman Act.[46] India's statutory Bolar exemption is broader than its U.S. counterpart, as it permits regulatory submissions not only in India but in any country, a provision of considerable significance given India's role as a supplier of generic medicines to the developing world.

4. The Constitutional Foundations of the Right to Health

4.1.Article 21 and the Right to Health

Article 21 of the Constitution of India provides that no person shall be deprived of life or personal liberty except according to procedure established by law. The Supreme Court has interpreted the right to life broadly, holding that it encompasses the rights to health, access to medical care, and to live with human dignity.[47]

In State of Punjab v. Mohinder Singh Chawla, the Court held that the right to health is integral to the right to life and that the state has an obligation to maintain health services.[48] In Paschim Banga Khet Mazdoor Samity v. State of West Bengal, the Court directed the government to ensure the availability of adequate medical facilities, holding that failure to provide timely medical treatment to a person in need violates Article 21.[49] In *Laxmi Mandal v. Union of India*, the Delhi High Court held that the denial of medical treatment to a pregnant woman resulting in her death constituted a violation of the right to life under Article 21 and the right to health

[43] *The Patents Act, 1970*, § 107A (as amended 2002) (India).
[44] Correa Carlos, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* 36–42 (South Centre 2000).
[45] R*oche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984).
[46]Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e
[47] *Bandhua Mukti Morcha v. Union of India*, (1984) 3 SCC 161, ¶ 10; *State of Punjab v. Mohinder Singh Chawla*, (1997) 2 SCC 83, ¶ 7; *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, (1996) 4 SCC 37, ¶ 9.
[48] S*tate of Punjab v. Mohinder Singh Chawla*, (1997) 2 SCC 83, ¶ 7.
[49]] *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, (1996) 4 SCC 37, ¶¶ 9–11.

ISSN: 2582-6433

under Article 47.[50]

The extension of Article 21 to encompass the right to access essential medicines follows from these authorities. If the state has a positive obligation to provide medical treatment, and if patent-protected drug prices render essential medicines inaccessible to the poor, then the state's patent policies, by creating and enforcing patent monopolies that raise drug prices, implicate Article 21. The argument is not that Article 21 prohibits patent protection altogether; rather, the state's patent policies must be calibrated to avoid creating a regime in which the right to health is subordinated to the right to exclude.

4.2.Article 14 and Non-Arbitrariness

Article 14, which guarantees equality before law and equal protection of law, and prohibits arbitrary state action, provides an additional constitutional basis for scrutinising pharmaceutical patent policies.[51] If the state grants a patent that enables a pharmaceutical company to charge a price that renders a life-saving drug inaccessible to the vast majority of the population, the grant of that patent and the state's failure to deploy TRIPS flexibilities such as compulsory licensing may be challenged as arbitrary and unreasonable.

The Supreme Court's judgment in Novartis implicitly engaged this reasoning. By upholding Section 3(d) against a challenge that it was arbitrary or unconstitutional, the Court endorsed the position that India's patent regime may indeed incorporate public health safeguards without violating the principle of non-discrimination or equal treatment.[52]

4.3.Directive Principles: Articles 39(b), 41, and 47

The Directive Principles of State Policy, though not judicially enforceable, provide the normative foundation for India's constitutional commitment to health. Article 39(b) directs the state to ensure that the ownership and control of the material resources of the community are so distributed as best to subserve the common good.[53] Article 41 directs the state to make effective provision for securing the right to work, education, and public assistance in cases of unemployment, old age, sickness, and disablement.[54] Article 47 directs the state to raise the

[50] *Laxmi Mandal v. Union of India*, WP(C) 8853/2008 (Delhi H.C. 2010).
[51] *E.P. Royappa v. State of Tamil Nadu*, (1974) 4 SCC 3, ¶ 7.
[52] *Novartis AG v. Union of India*, (2013) 6 SCC 1, ¶¶ 108–18.
[53] *Constitution of India*, art. 39(b).
[54] *Id.* art. 41.

ISSN: 2582-6433

level of nutrition and the standard of living of its people, and the improvement of public health as among its primary duties.[55]

These provisions, read together with the fundamental rights in Part III, establish a constitutional hierarchy: the right to health is not merely a policy aspiration but a justiciable right, and the state's patent policies must be consistent with the obligation to make essential medicines accessible. As the Supreme Court observed in Francis Coralie Mullin v. Union of India, the right to life includes the right to the bare necessities of life, and the state's obligation to secure these necessities cannot be overridden by the claims of private property.[56]

5. The International Legal Framework: TRIPS, Doha, and the Right to Health

5.1. TRIPS Flexibilities

TRIPS is often perceived as a monolithic instrument that mandates strong patent protection at the expense of public health. In reality, TRIPS contains several flexibilities that member states may deploy to protect public health. Article 8(1) permits members to adopt measures necessary to protect public health and nutrition, provided that such measures are consistent with the provisions of the TRIPS Agreement.[57] Article 30 permits limited exceptions to patent rights, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.[58] Article 31 permits compulsory licensing, subject to specified conditions including prior negotiation with the patent holder on reasonable commercial terms, adequate remuneration to the patent holder, and judicial or independent review of the licence and remuneration.[59]

India's patent regime incorporates these flexibilities. Section 3(d) is arguably an Article 30 exception, a limited exception that excludes certain subject matter from patentability without impairing the normal exploitation of genuine inventions. Compulsory licensing under Section 84 implements Article 31. The Bolar exemption under Section 107A implements Article 30. India has thus far been cautious in deploying these flexibilities; the *Natco* compulsory licence remains the only one granted, but the legal infrastructure exists for more assertive use.

[55] *Id.* art. 47.
[56] *Francis Coralie Mullin v. Union of India*, (1981) 1 SCC 368, ¶ 6.
[57] TRIPS Agreement, *supra* note 6, art. 8(1).
[58] *Id.* art. 30.
[59] *Id.* art. 31.

ISSN: 2582-6433

5.2.The Doha Declaration on TRIPS and Public Health

The Doha Declaration on TRIPS and Public Health, adopted at the WTO Ministerial Conference in Doha on November 14, 2001, affirmed that TRIPS should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.[60] Paragraph 4 of the Declaration explicitly states that the Agreement can and should be interpreted in a manner supportive of the right to protect public health.[61] Paragraph 5(b) confirms that each member has the freedom to determine what constitutes a national emergency or circumstances of extreme urgency, including public health crises such as those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics.[62] Paragraph 6 addresses the problem of countries with insufficient or no manufacturing capacity in the pharmaceutical sector, which cannot make effective use of compulsory licensing because they lack the domestic facilities to produce generic medicines.[63]

The Doha Declaration is not a treaty amendment; it is an interpretative statement by the WTO membership. Its legal effect has been debated, but it carries significant political and normative weight as a decision of the WTO Ministerial Conference, the WTO's highest decision-making body.[64] For India, the Doha Declaration provides authoritative confirmation that TRIPS flexibilities may be deployed to protect public health, and that the determination of what constitutes a public health crisis is a matter of national discretion.

5.3. The Right to Health under International Law

The right to health is recognised in several international instruments. Article 12 of the International Covenant on Economic, Social and Cultural Rights recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.[65] Article 12(2)(d) specifically requires states to take steps necessary to create conditions that would ensure medical services and medical attention in the event of sickness.[66] General Comment No. 14 of the Committee on Economic, Social and Cultural Rights interprets Article 12 as imposing an obligation on states to ensure the availability, accessibility, acceptability,

[60] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Declaration], ¶ 4.
[61] *Id.* ¶ 4.
[62] *Id.* ¶ 5(b).
[63] *Id.* ¶ 6.
[64] Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 44 *J. World Trade* 291 (2002
[65] International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, art. 12.
[66] *Id.* art. 12(2)(d).

ISSN: 2582-6433

and quality of health goods, facilities, and services.[67] Accessibility has four dimensions: non-discrimination, physical accessibility, economic accessibility (affordability), and information accessibility.[68]

The Committee has explicitly addressed the relationship between intellectual property and the right to health, stating that states must ensure that the application of international intellectual property regimes does not undermine the right to health and that states have a duty to prevent unreasonably high costs for access to essential medicines.[69] The Human Rights Council has adopted several resolutions affirming the primacy of the right to health over intellectual property rights, including Resolution 12/24, which states that access to medicines is a fundamental element of the right to health.[70]

6. Towards a Framework for Rebalancing: Proposals and Perspectives

6.1.Assertive Use of Compulsory Licensing

India's compulsory licensing regime is among the most robust in the developing world, yet it has been invoked only once. This reticence is puzzling. The conditions for compulsory licensing under Section 84, unmet public demand, unaffordable pricing, and non-working of the patent, are prevalent across numerous patented drugs in India. The Natco precedent provides a clear legal pathway; what is lacking is the political will to use it.

India should adopt a systematic approach to compulsory licensing of essential medicines priced beyond the reach of the Indian population. This does not mean indiscriminate licensing; it means that the government should identify patented essential medicines priced at levels incompatible with the right to health and be prepared to grant compulsory licenses where voluntary licensing on reasonable terms is not forthcoming. The threat of compulsory licensing is itself a negotiating tool; it incentivises patent holders to offer voluntary licenses at affordable prices, as the Medicines Patent Pool has demonstrated in the context of HIV and hepatitis C medicines.[71]

[67] U.N. Econ. & Soc. Council, *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, ¶ 12, U.N. Doc. E/C.12/2000/4 (2000
[68] *Id.* ¶ 12(b).
[69] *Id.* ¶¶ 35, 45.
[70] U.N. Hum. Rts. Council, *Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, Res. 12/24, U.N. Doc. A/HRC/RES/12/24 (2009).
[71] Medicines Patent Pool, *Annual Report 2022* 14–21 (2023).

ISSN: 2582-6433

6.2. Strengthening Section 3(d): Raising the Innovation Threshold

Section 3(d) has been India's most effective weapon against evergreening, but its application has been inconsistent. The patent office has granted patents on new forms of known substances in which the claimed enhancement in efficacy has been marginal or dubious.[72] The Supreme Court's *Novartis* judgment established the principle that therapeutic efficacy, not mere bioavailability, stability, or processing convenience, is the relevant standard, but the patent office and the IPAB have not always applied this standard rigorously.

Two reforms are necessary. First, the patent office should issue detailed guidelines for applying Section 3(d), specifying the nature and quantum of evidence required to demonstrate enhanced therapeutic efficacy. The guidelines should require clinical data, not merely in vitro data or pharmacokinetic studies, as the benchmark for establishing enhanced efficacy. Second, the standard of review for Section 3(d) decisions should be heightened. Pre-grant opposition under Section 25(1) and post-grant opposition under Section 25(2) are powerful tools, but they are effective only if oppositions are filed and adjudicated competently.[73] Civil society organisations and generic manufacturers should be encouraged and supported in filing oppositions, and the patent office should ensure that opposition proceedings are not used by patent applicants as instruments of delay.

6.3. Government Use Licensing under Section 92

Section 92 of the Patents Act empowers the Central Government to authorise the use of a patented invention for government purposes, or in circumstances of national emergency or extreme urgency, or in cases of public non-commercial use.[74] Unlike compulsory licensing under Section 84, government use licensing under Section 92 does not require prior negotiation with the patent holder, and the government may authorise any person to use the patent.[75] Section 92(3) provides that in cases of national emergency or extreme urgency, the requirement to grant the patent holder a hearing may be dispensed with, though the patent holder must be notified as soon as practicable.[76]

[72] Anubha Sinha, *Section 3(d) of the Indian Patents Act: The Experiences of a Decade*, 59 *J. Indian L. Inst.* 464 (2017)
[73] *The Patents Act, 1970*, §§ 25(1), 25(2) (as amended 2005) (India).
[74] *Id.* § 92(1).
[75] *d.* § 92(1)(a)–(c).
[76] *Id.* § 92(3).

ISSN: 2582-6433

Section 92 is a more powerful instrument than Section 84, but it has never been used. This is a significant gap in India's public health toolkit. In Thailand, the government issued government-use licences for the HIV drug efavirenz in 2006 and the cancer drug letrozole in 2008, dramatically reducing prices without triggering the catastrophic consequences that the pharmaceutical industry had predicted.[77] India should be prepared to invoke Section 92 in cases of public health emergencies, a category that should encompass not only epidemics but also situations where patented essential medicines for life-threatening conditions are priced beyond the reach of the population.

6.4. Comparative Perspectives: South Africa, Brazil, and Thailand

South Africa's experience illustrates both the potential and the peril of asserting TRIPS flexibilities. The Medicines and Related Substances Control Amendment Act of 1997 authorised the South African Health Minister to permit parallel importation and compulsory licensing for medicines.[78] The Pharmaceutical Manufacturers Association of South Africa, representing thirty-nine pharmaceutical companies, challenged the Act in court, alleging that it violated TRIPS and the South African Constitution.[79] The case was withdrawn in 2001 after an extraordinary global campaign by civil society organisations, but the episode demonstrated the political costs of asserting public health rights against pharmaceutical patent interests.[80]

Brazil adopted a more proactive approach. The 1996 Industrial Property Law authorised compulsory licensing in cases of national emergency, including public health crises, and Brazil threatened compulsory licensing for several HIV drugs in the early 2000s, securing significant price reductions through voluntary agreements with patent holders.[81] Brazil's strategy demonstrated that the credible threat of compulsory licensing can achieve outcomes that may not require the formal invocation of the mechanism.

Thailand's experience with government use licensing under Section 92-equivalent provisions

[77] Kannikar Kijtiwatchakul, *Thailand's Government Use Licences: Four Years On*, 16 *J. World Intellect. Prop.* 298 (2013).
[78] *Medicines and Related Substances Control Amendment Act, 1997*, No. 90 of 1997 (S. Afr.).
[79] *Pharmaceutical Manufacturers Association of South Africa v. President of the Republic of South Africa*, Case No. 4183/98 (Transvaal Prov. Div., withdrawn Apr. 19, 2001).
[80] Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 *Chicago J. Int'l L.* 27 (2002).
[81] Brazil, *Law No. 9,279 of May 14, 1996* (Industrial Property Law), arts. 68–73; see also Amy Nunn et al., *Changing Global Policy to Improve Access to Medicines: The Brazilian Experience*, in *African Politics* 105 (2007).

ISSN: 2582-6433

demonstrated that middle-income countries can use TRIPS flexibilities effectively without suffering catastrophic consequences.[82] Prices for efavirenz fell by over 50% after the Thai government issued a government-use licence, and the predicted collapse of foreign investment did not materialise.[83]

6.5. The Post-TRIPS Landscape: COVID-19 and the TRIPS Waiver

The COVID-19 pandemic brought the patent-health tension into sharpest relief. In October 2020, India and South Africa proposed a waiver of certain TRIPS provisions, patents, copyrights, industrial designs, and trade secrets for the prevention, containment, and treatment of COVID-19.[84] The proposal was supported by over 100 WTO members but faced fierce opposition from the European Union, Switzerland, and the United Kingdom.[85] The waiver that was ultimately adopted in June 2022, the Ministerial Decision on the TRIPS COVID-19 Waiver, was a profoundly diluted version of the original proposal, covering only vaccines and imposing significant procedural requirements.[86]

The COVID-19 experience exposed the inadequacy of the existing TRIPS framework for addressing global health emergencies. The waiver process was too slow, the outcome too narrow, and the political dynamics too skewed toward the interests of pharmaceutical-producing countries.[87] For India, the lesson is clear: it cannot rely on multilateral processes to protect its public health interests in a crisis. It must develop domestic legal instruments, including compulsory licensing, government use licensing, and a robust interpretation of Section 3(d), that enable swift action when the right to health is at stake.

7. Conclusion

The tension between patents and patients is not a problem that admits of a single, elegant solution. Patents serve a legitimate purpose; they incentivise the research and development that produces new medicines. But the incentive function of patents does not operate in a vacuum; it operates within a constitutional and moral framework that prioritises the rights to life and

[82] Kijtiwatchakul, *supra* note 77, at 302–06.
[83] *Id.* at 310.
[84] World Trade Organization, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, Communication from India and South Africa, IP/C/W/669 (Oct. 2
[85] *Id.*; see also Brook K. Baker, *The Proposed COVID-19 TRIPS Waiver*, 23 *Medical Access & Pricing* 1 (2021)
[86] Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30 (June 17, 2022).
[87] Srividya Ravindhran & Muhammad Zaheer Abbas, *The TRIPS COVID-19 Waiver: Too Little, Too Late?*, 36 *Emory Int'l L. Rev.* 45 (2022).

ISSN: 2582-6433

health. When patent monopolies render essential medicines unaffordable for the people who need them, the patent system is not serving its social purpose; it is subverting it.

India has the legal tools to rebalance pharmaceutical intellectual property and the right to health. Section 3(d) is a TRIPS-consistent safeguard against evergreening that the Supreme Court has authoritatively upheld. Compulsory licensing under Section 84 is a powerful mechanism for ensuring access, as the Natco decision demonstrated. Government use of licensing under Section 92 remains an unused but potent instrument for emergencies. The Bolar exemption under Section 107A enables generic market entry upon patent expiry. The Doha Declaration and the international right to health framework provide normative legitimacy for the assertive deployment of these flexibilities.

What India lacks is not legal authority but political will. The *Natco* compulsory licence remains the only one granted in over a decade of product patent protection. Section 3(d) has been inconsistently applied. Section 92 has never been invoked. The result is a patent regime that, on paper, incorporates robust public health safeguards but, in practice, has been insufficiently deployed to protect the right to health of India's 1.4 billion people.

The framework proposed in this article rests on three pillars. First, India must use its existing TRIPS flexibilities more assertively, granting compulsory licences for essential medicines priced beyond the reach of the population and invoking government use licensing in public health emergencies. Second, it must strengthen the application of Section 3(d) by issuing clear guidelines that require clinical evidence of enhanced therapeutic efficacy and by encouraging robust pre- and post-grant opposition. Third, it must embed the right to health as a constitutional constraint on the operation of the patent system so that the grant and enforcement of pharmaceutical patents are always subject to the overriding imperative of access to medicines. These proposals are not anti-patent. They recognise that innovation and access are complementary, not contradictory, goals. A patent system that enables evergreening without therapeutic advance, that permits monopoly pricing for essential medicines, and that subordinates the right to health to the right to exclude is not a system that promotes innovation it is a system that perpetuates inequality. India's constitutional commitments demand a better balance. The legal instruments exist. What remains is the courage to use them.