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(SOVEREIGN NYAYA VS. CORPORATE MONOPOLY: A CRITICAL
DOCTRINAL ANALYSIS OF PHARMACEUTICAL PATENT
EVERGREENING, COMPULSORY LICENSING, AND THE CRIMINAL
REGULATION OF SPURIOUS DRUGS IN INDIA)

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Abstract

India occupies a unique geopolitical and jurisprudential position in global public health. Celebrated as the "*Pharmacy of the Developing World*" for supplying over twenty percent of the world's generic medicines and sixty percent of global vaccines, the Indian pharmaceutical ecosystem sits at the epicenter of an intense constitutional and statutory tug-of-war. On one side lies the international obligation to protect private intellectual property rights under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); on the other stands the non-negotiable fundamental right to health and affordable life-saving medicine guaranteed under Article 21 of the Constitution of India. This research paper undertakes a comprehensive doctrinal examination of the four foundational pillars governing **Pharmaceutical Jurisprudence in India**. First, it dissects the statutory bulwark against "patent evergreening" under **Section 3(d) of the Patents Act, 1970**, evaluating how the Supreme Court's landmark ruling in *Novartis AG v. Union of India* redefined the threshold of "enhanced therapeutic efficacy." Second, it analyzes the Sovereign

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Compulsory Licensing mechanism under **Sections 84 and 92 of the Patents Act** (*Natco Pharma v. Bayer Corporation*) alongside the persistent diplomatic pressures for TRIPS-Plus "Data Exclusivity." Third, it exposes the systemic regulatory schism between penalizing lethal "**Spurious Drugs**" and decriminalizing minor compound deviations under the **Drugs and Cosmetics Act, 1940** (as amended by the *Jan Vishwas (Amendment of Provisions) Act, 2023*) and **Sections 276 to 278 of the Bharatiya Nyaya Sanhita, 2023 (BNS)**. Finally, it critiques the statutory regime governing clinical trial compensation under the **New Drugs and Clinical Trials Rules, 2019**, proposing a unified central drug regulatory architecture to eliminate interstate enforcement arbitrage.

Keywords: *Pharmaceutical Jurisprudence, Section 3(d) Patents Act 1970, Patent Evergreening, Novartis v. Union of India, Compulsory Licensing Section 84, Spurious vs. Substandard Drugs, Jan Vishwas Act 2023, Sections 276–278 Bharatiya Nyaya Sanhita, Clinical Trial Liability.*

1. Introduction: The Constitutional Mandate of Pharmaceutical Jurisprudence

Unlike ordinary consumer commodities where market forces of supply, demand, and price elasticity can operate with minimal state intervention a life-saving pharmaceutical molecule is intimately bound to human survival. In a consumer transaction for an oncology drug or an antiretroviral therapy, the patient exercises zero bargaining power; the alternative to purchasing the medicine is physical deterioration or death. Consequently, the regulation of pharmaceuticals represents one of the most delicate intersections of **Intellectual Property Law, Constitutional Human Rights, Criminal Law, and Administrative Regulation.**

In Indian constitutional jurisprudence, the right to health and access to affordable medical treatment is not merely a non-enforceable aspiration under the Directive Principles of State Policy (Article 47); it has been judicially crystallized as an integral component of the **Right to Life under Article 21 of the Constitution** (*Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, 1996 4 SCC 37; *Union of India v. Moolchand Khairati Ram Trust*, 2018 8 SCC 321).

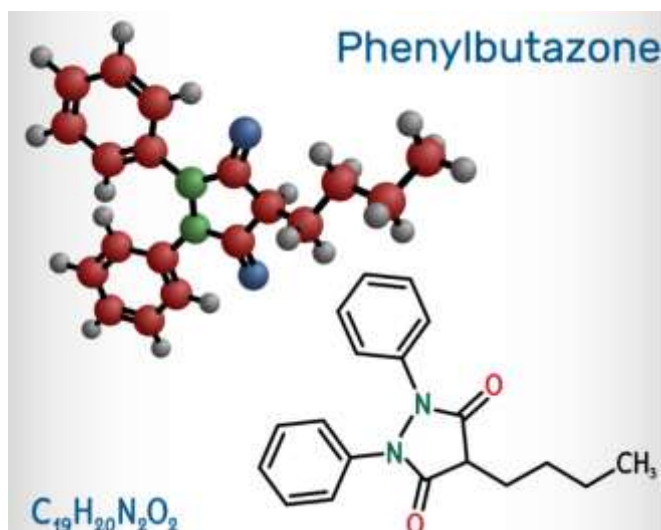
Historically, India's rise as a global powerhouse of affordable generic medicines was directly enabled by a bold legislative choice made in **The Patents Act, 1970** (based on the Justice N. Rajagopala Ayyangar Committee Report of 1959). By enacting the former Section 5 of the 1970 Act, Parliament deliberately abolished *product patents* for substances intended for use as food, medicine, or drugs, granting only short-term *process patents*. This allowed Indian pharmaceutical scientists to reverse-engineer patented Western molecules through novel, non-infringing chemical pathways, slashing the cost of essential treatments such as HIV/AIDS triple-combination antiretroviral therapy from over \$10,000 per patient per year to less than \$150.

However, India's accession to the World Trade Organization (WTO) and the **TRIPS Agreement** in 1995 mandated a transition back to a full twenty-year product patent regime for pharmaceuticals by January 1, 2005. Faced with the existential threat that multinational pharmaceutical corporations ("Big Pharma") would monopolize essential medicines and price millions of Indian citizens out of survival, Parliament enacted the **Patents (Amendment) Act, 2005**. Rather than surrendering domestic public health sovereignty, Indian lawmakers engineered a sophisticated set of TRIPS-compliant statutory safeguards most notably **Section 3(d)** and **Section 84** which have since become the gold standard for public-health-sensitive intellectual property law across the Global South.

2. The Anti-Evergreening Bulwark: Section 3(d) of the Patents Act, 1970 and Novartis AG

2.1 The Mechanics of Secondary Patenting ("Evergreening")

In the pharmaceutical industry, discovering a genuinely novel New Chemical Entity (NCE) requires substantial capital investment and clinical trial gestation. Once the twenty-year primary product patent on an active pharmaceutical ingredient (API) nears expiration, innovator corporations routinely deploy a legal-scientific strategy known as "**Patent Evergreening.**"



As illustrated in the molecular structure above, a pharmaceutical compound can exist in multiple polymorphic forms, salts, esters, ethers, isomers, or particle sizes. Under the permissive patent standards of the United States (35 U.S.C. § 101) and the European Patent Convention, corporations routinely file clusters of secondary patents on minor, predictable chemical variations of an existing drug such as converting a free base into a more stable crystalline salt, creating an extended-release tablet coating, or isolating a single enantiomer thereby extending their commercial monopoly well beyond the original twenty-year statutory term and blocking generic competition.

2.2 The Statutory Architecture of Section 3(d)

To foreclose this loophole, Parliament amended **Section 3(d) of the Patents Act, 1970** in 2005 to declare that the following are **not inventions** within the meaning of the Act:

"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 or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes,

combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

By creating a **statutory legal fiction** that all derivatives, salts, and polymorphs of a known substance are deemed to be the "*same substance*," Section 3(d) shifts the burden onto the patent applicant to prove a heightened statutory threshold: a significant enhancement in **efficacy**.

2.3 Doctrinal Analysis of *Novartis AG v. Union of India* (2013)

The constitutional and interpretive contours of Section 3(d) were definitively tested before the Supreme Court of India in *Novartis AG v. Union of India & Ors.*, (2013) 6 SCC 1. The dispute centered on **Imatinib Mesylate** (marketed globally as *Glivec/Gleevec*), a life-saving drug used to treat Chronic Myeloid Leukemia. Novartis had already disclosed the base molecule (*Imatinib*) and its pharmaceutically acceptable salts in its 1993 Zimmermann Patent in the United States. In 1998, Novartis applied for an Indian patent on a specific polymorphic crystal form the **Beta-Crystalline form of Imatinib Mesylate** claiming that this new form exhibited superior thermodynamic stability, reduced hygroscopicity, improved flow properties, and a **30% increase in bioavailability** compared to the free base.

Writing for the Division Bench, Justice Aftab Alam delivered a landmark judgment that established three enduring principles of Indian pharmaceutical patent law:

1. **Strict Interpretation of "Efficacy" as "Therapeutic Efficacy":** When the "known substance" in question is a pharmaceutical drug, the word "*efficacy*" in Section 3(d) means "**therapeutic efficacy**" and nothing else. It denotes the capacity of a medicine to produce a desired curative or healing effect on a pathology in the human body.
2. **Physicochemical Improvements Do Not Equal Therapeutic Efficacy:** Mere improvements in physical or processing characteristics such as better

shelf-life, easier tableting, higher water solubility, or heat stability pertain to *formulation convenience*, not *curative power*, and therefore cannot cross the Section 3(d) bar.

3. **Bioavailability is Not Automatically Therapeutic Efficacy:** Rejecting Novartis's argument that a 30% increase in blood bioavailability automatically proved enhanced efficacy, the Court held that whether increased bioavailability translates into a demonstrably superior therapeutic outcome in a patient (such as reduced toxicity or higher cure rates) must be proven strictly through **empirical clinical data**, not theoretical pharmacological assumptions.

3. Sovereign Compulsory Licensing and the TRIPS-Plus "Data Exclusivity" Threat

3.1 The Compulsory Licensing Trilogy under Sections 84, 92, and 92A

Even where a multinational corporation successfully obtains a valid product patent on a genuinely novel drug, the monopoly granted under Section 48 of the Patents Act is conditional upon fulfilling the public interest benchmarks enshrined in **Section 83** (specifically, that patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article, and that they must never impede protection of public health).

To enforce this social contract, **Section 84(1) of the Patents Act, 1970** empowers any interested person, after the expiration of three years from the date of grant of a patent, to apply to the Controller of Patents for a **Compulsory Licence (CL)** on any of three independent statutory grounds:

- **Section 84(1)(a):** That the **reasonable requirements of the public** with respect to the patented invention have not been satisfied; or
- **Section 84(1)(b):** That the patented invention is **not available to the public at a reasonably affordable price**; or

- **Section 84(1)(c):** That the patented invention is **not worked in the territory of India.**

In India's first and most celebrated post-TRIPS compulsory licensing decision, *Natco Pharma Ltd. v. Bayer Corporation* (Compulsory Licence Application No. 1 of 2011; affirmed by the Bombay High Court in *Bayer Corporation v. Union of India*, AIR 2014 Bom 178, and SLP dismissed by the Supreme Court in 2014), the Controller granted a compulsory licence to Natco to manufacture a generic version of Bayer's patented kidney and liver cancer drug **Sorafenib Tosylate (Nexavar)**. Bayer had priced *Nexavar* at an exorbitant **Rs. 2,80,428 per month** reaching less than 2% of eligible Indian cancer patients and imported the drug in small quantities rather than manufacturing it locally. Under the compulsory licence, Natco supplied the identical therapy at **Rs. 8,800 per month** (a 97% price reduction) while paying a 6% royalty on net sales to Bayer.

However, a critical empirical critique must be noted: since *Natco v. Bayer* in 2012, subsequent compulsory licence applications (such as *BDR Pharmaceuticals v. Bristol-Myers Squibb* for Dasatinib and *Lee Pharma v. AstraZeneca* for Saxagliptin) have been routinely rejected on procedural thresholds specifically the failure of the generic applicant to establish a "*prima facie case*" of satisfying the public requirement or prolonged negotiations with the patentee. This reveals an administrative reluctance to invoke Section 84 or **Section 92** (suo motu Government Notification in circumstances of national emergency or extreme urgency) due to bilateral trade pressures.

3.2 The "Data Exclusivity" Loophole in Bilateral Free Trade Agreements (FTAs)

Recognizing that Section 3(d) and Section 84 cannot easily be dismantled through domestic litigation, developed-nation trade negotiators increasingly push for "**Data Exclusivity**" in Free Trade Agreements (such as the EFTA and UK-India FTA negotiations).

Under the current Indian regulatory framework (**New Drugs and Clinical Trials Rules, 2019** under the Drugs and Cosmetics Act, 1940), when a generic manufacturer applies to the **Central Drugs Standard Control Organization**

(CDSCO) for marketing approval of an off-patent or unpatented drug, the generic company does not have to repeat expensive, ethically questionable Phase I–III human clinical trials; it simply proves **bioequivalence** to the innovator's reference drug, while the CDSCO relies indirectly on the safety and efficacy data originally submitted by the innovator.

The Loophole: If India were to accept a TRIPS-Plus "Data Exclusivity" clause (going beyond the mere protection against "*unfair commercial use*" under **Article 39.3 of TRIPS**), the CDSCO would be legally barred from relying on the innovator's clinical trial dossier for a fixed period (typically 5 to 10 years), **even if the drug failed Section 3(d) and had no patent in India, or even if a Compulsory Licence was issued under Section 84!** Data exclusivity thus acts as a backdoor "shadow monopoly" that can completely paralyze both Section 3(d) and Compulsory Licensing without ever entering the Patent Office.

4. Criminal Liability for "Spurious" vs. "Substandard" Drugs: The Statutory Schism

While intellectual property law governs the *availability and price* of medicines, criminal and regulatory law governs their *safety, purity, and pharmacopoeial integrity*. In the wake of recent global and domestic tragedies such as the fatal Diethylene Glycol (DEG) and Ethylene Glycol contamination of paediatric cough syrups the legal regulation of drug quality has become a pressing crisis in Indian jurisprudence.



4.1 The Crucial Statutory Distinction: Section 17B vs. Section 16 of the Drugs and Cosmetics Act, 1940

As highlighted in the quality-control inspection visual above, physical pills that appear identical to the naked eye may conceal two fundamentally different legal infractions under the **Drugs and Cosmetics Act, 1940**:

1. **Spurious Drugs (Section 17B):** A drug is legally deemed "**Spurious**" when it is manufactured under a name which belongs to another drug; or is an imitation of, or substitute for, another drug in a manner likely to deceive; or its label bears the name of a fictitious individual or company purporting to be its manufacturer; or **it has been substituted wholly or in part by another drug or substance** (e.g., chalk tablets sold as antibiotics, or toxic industrial Diethylene Glycol substituted for pharmaceutical-grade Propylene Glycol solvent). Under **Section 27(a) of the Drugs and Cosmetics Act**, manufacturing or selling a spurious or adulterated drug that is likely to cause death or grievous hurt attracts a minimum sentence of **ten years imprisonment extendable to imprisonment for life**, and a fine of not less than ten lakh rupees or three times the value of the drugs confiscated.
2. **Not of Standard Quality (NSQ / "Substandard" Drugs) (Section 16):** Conversely, a drug is categorized as "**Not of Standard Quality**" (NSQ) when it is manufactured by a genuine, licensed pharmaceutical company, contains the genuine active ingredient, and involves no fraudulent counterfeiting, but fails to meet one or more technical parameters prescribed in the *Indian Pharmacopoeia* (for example, failing a tablet dissolution test in 45 minutes due to tropical humidity during transit, or assaying at 88% of the stated active ingredient instead of the mandated 90%–110% range).

4.2 The *Jan Vishwas Act, 2023* Loophole and the *Mens Rea* Dilemma

Historically, state Drug Inspectors frequently prosecuted minor technical NSQ failures (such as a slight pH variation or minor tablet friability issue) alongside genuine counterfeiters in slow criminal trials. To promote "Ease of Doing Business" and decriminalize minor technical defaults, Parliament enacted the **Jan Vishwas (Amendment of Provisions) Act, 2023**, which amended **Section 27(d) and Section 32B of the Drugs and Cosmetics Act, 1940**, enabling the **compounding (monetary settlement) of offences** relating to generic NSQ deviations.

The Doctrinal Critique and Regulatory Loophole: While decriminalizing genuinely minor, non-hazardous packaging or moisture defects is rational, the statutory boundary between a "compoundable NSQ defect" under Section 27(d) and a "life-threatening pharmacological failure" under Section 27(a) is dangerously porous in practice. When a life-saving antibiotic or cardiac injection contains only 40% of its required active pharmaceutical ingredient due to reckless manufacturing shortcuts or lack of stability testing, treating it merely as a compoundable "Not of Standard Quality" infraction resolvable by paying a modest administrative fine without criminal trial or mandatory public recall creates a catastrophic moral hazard for patient safety.

4.3 Interplay with Sections 276, 277, and 278 of the Bharatiya Nyaya Sanhita, 2023 (BNS)

Parallel to the special regime of the Drugs and Cosmetics Act, the newly enacted **Bharatiya Nyaya Sanhita, 2023** retains general penal provisions targeting drug adulteration:

- **Section 276 BNS (formerly Section 274 IPC):** Adulteration of drugs so as to lessen their efficacy, change their operation, or make them noxious.
- **Section 277 BNS (formerly Section 275 IPC):** Sale of adulterated drugs knowing the same to have been adulterated.
- **Section 278 BNS (formerly Section 276 IPC):** Sale of a drug as a different drug or preparation.

However, a glaring anomaly persists in the BNS: **Sections 276 and 277 of the BNS prescribe a maximum punishment of only one year (or six months) imprisonment and a fine of five thousand rupees!** Furthermore, because Section 32 of the Drugs and Cosmetics Act bars ordinary police officers from prosecuting specialized drug-manufacturing offences (reserving cognizance to notified Drug Inspectors, as examined by the Supreme Court in ***Union of India v. Ashok Kumar***

Sharma, 2020 SCC OnLine SC 683), unscrupulous manufacturers caught by local police often attempt to challenge police FIRs on jurisdictional grounds, while Drug Inspectors remain severely understaffed across state boundaries.

5. Clinical Trial Ethics and Strict Compensation Liability in India

As India serves as a major hub for global Phase II and Phase III clinical trials, the legal protection of human trial subjects who are frequently drawn from economically vulnerable populations constitutes a vital pillar of pharmaceutical law.

Following a scathing public interest litigation in *Swasthya Adhikar Manch, Indore & Anr. v. Ministry of Health & Family Welfare* (W.P. (C) No. 33 of 2012) which exposed hundreds of uncompensated deaths and failures of informed consent during clinical trials the Supreme Court halted erratic approvals and forced a complete overhaul of India's clinical trial framework, culminating in the **New Drugs and Clinical Trials (NDCT) Rules, 2019**.

Under **Chapter VI (Rules 39 to 43) of the NDCT Rules, 2019**, India instituted one of the world's most stringent statutory regimes for **Clinical Trial Injury and Death Compensation**:

1. **Mandatory Free Medical Management (Rule 39(1))**: Where any trial subject suffers an injury during a clinical trial or bioavailability/bioequivalence study, the sponsor must provide free medical management for as long as required in the opinion of the investigator or the Institutional Ethics Committee (IEC).
2. **Broad Causation Triggers for Financial Compensation (Rule 41)**: Unlike traditional tort law where a victim must prove that the experimental drug directly and exclusively caused the injury Rule 41 mandates financial compensation if the injury or death is related to *any* of the following: (a) an adverse effect of the investigational product; (b) any violation of the approved protocol, scientific misconduct, or negligence by the sponsor or

investigator; (c) **failure of the investigational product to provide its intended therapeutic effect** where standard care was withheld; (d) **use of a placebo** in a placebo-controlled trial where standard care was denied; or (e) any clinical trial procedure itself.

3. **Mandatory Audio-Video Recording of Informed Consent:** For vulnerable populations and specific new chemical entity trials, informed consent cannot be a mere thumbprint on an English document; the process of explaining risks in the subject's vernacular language must be documented with strict ethics committee oversight.

6. Structural Recommendations and Conclusion

To harmonize India's twin roles as a global pharmaceutical manufacturing titan and a constitutional welfare state committed to *Nyaya*, four structural legal reforms are imperative:

6.1 Enactment of a Unified Central Drug Authority (Eliminating Federal Licensing Arbitrage)

Currently, under the Drugs and Cosmetics Act, 1940, regulatory authority is splintered between the central **CDSCO** (headed by the Drugs Controller General of India - DCGI) and **36 separate State Drug Controllers (SDCs)**. Consequently, a pharmaceutical manufacturer whose drug is declared "Not of Standard Quality" in one state can continue obtaining manufacturing licenses in another state with weaker inspection capacity, and there is no mandatory, statutory **National Drug Recall Law** requiring immediate nationwide withdrawal of failed batches. Parliament must replace the colonial 1940 Act with an updated **Drugs, Medical Devices and Cosmetics Act** that establishes a unified central licensing database and a mandatory, statutory, time-bound **National Recall Mechanism**.

6.2 Statutory Codification of "Critical vs. Minor" NSQ Defects

To prevent the *Jan Vishwas Act, 2023* compounding provisions from shielding dangerous manufacturing negligence, Section 16 and Section 27(d) of the Drugs

and Cosmetics Act must be amended to follow the World Health Organization (WHO) three-tier risk classification:

- **Category A (Critical Defects):** Contamination with toxic solvents (such as DEG/EG), bacterial endotoxin contamination in injectables, or assay failures below 80% in life-saving medicines must be statutorily classified as **non-compoundable felony offences** on par with Spurious Drugs.
- **Category B & C (Major/Minor Technical Defects):** Only minor labelling errors, slight hardness variations, or non-hazardous excipient deviations should be eligible for administrative compounding under Section 32B.

6.3 Statutory Prohibition on "Data Exclusivity" in Domestic Law

To insulate Indian trade negotiators from bilateral TRIPS-Plus pressure, an explicit proviso should be inserted into **Section 122 of the Drugs and Cosmetics Act (and the NDCT Rules, 2019)** affirming that the Central Licensing Authority shall at all times be empowered to rely upon global clinical safety and bioequivalence data to approve generic and biosimilar medicines whenever no valid patent subsists under the Patents Act, 1970, or whenever a Compulsory Licence has been issued under Sections 84, 92, or 92A.

6.4 Harmonizing Punishments under Sections 276–278 of the BNS, 2023

The archaic, paltry sentence of six months to one year imprisonment and a Rs. 5,000 fine under **Sections 276 to 278 of the Bharatiya Nyaya Sanhita, 2023** for drug adulteration is wholly disproportionate to the gravity of the crime. Sections 276–278 BNS must be amended to mirror the severe sentencing structure of Section 27 of the Drugs and Cosmetics Act (up to ten years or life imprisonment where adulteration causes grievous hurt or death), alongside clear statutory coordination between Police Investigating Officers and Drug Inspectors.

Conclusion

The genius of Indian pharmaceutical jurisprudence lies in its refusal to treat intellectual property or corporate deregulation as ends in themselves. From Justice Ayyangar's 1959 blueprint to the Supreme Court's historic defense of Section 3(d) in *Novartis* and the activation of compulsory licensing in *Natco*, Indian law has consistently demonstrated that a patent is a privilege granted by the sovereign to serve public welfare, not a license to hold human life to ransom. Yet, affordable access is meaningless without uncompromised pharmacological quality. By fortifying the anti-evergreening walls of the Patents Act against TRIPS-Plus data exclusivity while simultaneously modernizing the criminal enforcement machinery against spurious and toxic drugs under the BNS and Drugs Regulation regime, India can truly fulfill both its constitutional promise under Article 21 and its ethical responsibility as the pharmacy of the world.

References & Authorities

1. Primary Indian Legislation & International Treaties:

- *The Patents Act, 1970* (Act 39 of 1970, as amended by Act 15 of 2005), §§ 2(1)(j), 2(1)(ja), 3(d), 3(e), 48, 83, 84, 92, 92A, 100.
- *The Drugs and Cosmetics Act, 1940* (Act 23 of 1940), §§ 16, 17, 17A, 17B, 18, 27, 32, 32B.
- *The Jan Vishwas (Amendment of Provisions) Act, 2023* (Act 18 of 2023).
- *The Bharatiya Nyaya Sanhita, 2023* (Act 45 of 2023), §§ 276, 277, 278.
- *The New Drugs and Clinical Trials Rules, 2019*, Gazette of India, G.S.R. 227(E) (Mar. 19, 2019), Rules 39–43.

- *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Arts. 27, 30, 31, 39.3; read with the *Doha Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 14, 2001).

2. Landmark Judicial Precedents:

- *Bayer Corporation v. Union of India & Ors.*, AIR 2014 Bom 178 : 2014 SCC OnLine Bom 963 (Affirming India's first post-TRIPS Compulsory Licence for Sorafenib Tosylate under Section 84 of the Patents Act).
- *F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd.*, (2015) 225 DLT 391 (DB) (Public interest and differential pricing principles in pharmaceutical patent injunctions concerning Erlotinib).
- *Novartis AG v. Union of India & Ors.*, (2013) 6 SCC 1 : AIR 2013 SC 1311 (Constitutionality and interpretation of "enhanced therapeutic efficacy" under Section 3(d) of the Patents Act, 1970).
- *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, (1996) 4 SCC 37 (Right to medical care and emergency health services as an enforceable fundamental right under Article 21).
- *Swasthya Adhikar Manch, Indore & Anr. v. Ministry of Health & Family Welfare & Ors.*, (2013) 10 SCC 732 (Supreme Court directives on ethical oversight and strict compensation in human clinical trials).
- *Union of India v. Ashok Kumar Sharma & Ors.*, (2021) 12 SCC 674 : 2020 SCC OnLine SC 683 (Jurisdictional division between Police

FIRs under the Penal Code and Drug Inspector complaints under Section 32 of the Drugs and Cosmetics Act, 1940).

3. Foundational Committee Reports & Doctrinal Literature:

- Ayyangar, N. R. (1959). *Report on the Revision of the Patents Law*. Government of India.
- Basheer, S., & Reddy, P. (2008). The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d). *SCRIPTed: A Journal of Law, Technology and Society*, 5(2), 232–266.
- Kapczynski, A. (2009). Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector. *California Law Review*, 97(6), 1571–1649.
- Mashelkar, R. A. (2003). *Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs*. Ministry of Health and Family Welfare, Government of India.
- Thakur, D. S., & Reddy, T. P. (2022). *The Truth Pill: The Myth of Drug Regulation in India*. Simon & Schuster India.