Jurnal Impresi Indonesia (JII)
p-ISSN: 2828-1284 e-ISSN: 2810-062x
website: https: //rivierapublishing.id/jii/index.php/
Vol. 4. No. 11. 2025

Justice and Regulation in Pharmaceutical Patents: A Comparative Philosophical Inquiry into India and Indonesia (1970–2024)

Raymond R. Tjandrawinata
Atma Jaya Catholic University of Indonesia, Indonesia
Email: raytjan@yahoo.com

Keywords

pharmaceutical patents; distributive justice; progressive law; regulatory capture; TRIPS.

Abstract

The theoretical framework draws on John Rawls's theory of distributive justice, Satjipto Rahardjo's concept of progressive law, and Barry Mitnick's theory of the political economy of regulation. This study analyzes the evolution of pharmaceutical patent regimes in India and Indonesia through a juridical-philosophical lens. The study uses a normative-doctrinal method involving textual analysis of legislation, judicial decisions, and policy documents, combined with historical-institutional analysis to identify three stages of legal learning: legal formalism, moral institutionalism, and reflective governance. Historical analysis reveals two epistemologically distinct trajectories. Since 1970, India has developed a legal system that balances exclusive rights and public welfare through substantive mechanisms such as Section 3(d), compulsory licensing, and drug price control under the National Pharmaceutical Pricing Authority (NPPA). Indonesia, by contrast, initially adopted a TRIPS-compliant positivist approach and began transitioning only in 2024 toward a more reflective and justice-oriented patent regime through the enactment of Law No. 65/2024 on Patents. The study argues that the fairness of a patent system should not be measured by its capacity to create monopolies of knowledge but by its effectiveness in distributing the benefits of technology to those most in need. It concludes with the formulation of a *Balanced Patent Justice Framework (BPJF)*, a normative model integrating Rawlsian fairness, Satjiptian humanism, and Mitnickian institutional design to construct a pharmaceutical patent regime that is not only efficient but also morally sustainable.

INTRODUCTION

Pharmaceutical patents occupy one of the most ethically charged domains of modern law, functioning simultaneously as instruments of economic progress and moral responsibility (Khachigian, 2020; Paes et al., 2020). On one hand, they safeguard scientific discovery by granting exclusive rights, offering assurance to inventors and investors that their innovations are legally protected. On the other hand, patents carry a latent potential for injustice, particularly when exclusivity translates into high drug prices and restricted access to essential medicines (Tenni et al., 2022; Suryahartati, 2024; Muis et al., 2025). The intersection of science, economics, and

morality thus transforms patent law into an ethical arena where the state's competence is tested: can it reconcile market rationality with its moral duty to preserve life?

John Rawls famously argues in A Theory of Justice that justice is the first virtue of social institutions. His difference principle holds that social and economic inequalities can be justified only if they benefit the least advantaged members of society (Premchand, 2017). When applied to pharmaceutical patents, this principle implies that commercial exclusivity, while stimulating innovation, must ultimately be evaluated in terms of its contribution to public welfare, especially among low-income populations. For Rawls, a just legal order is not one that is merely consistent or procedurally sound, but one that sustains an ethical equilibrium between individual freedom and collective well-being (Orji et al., 2025). A patent regime that fails to meet this equilibrium loses its moral legitimacy, regardless of its formal coherence.

Satjipto Rahardjo adds a distinctively humanistic dimension to this inquiry. In his conception of progressive law, law is never static; it is a living institution continuously moving toward its moral telos—the humanization of humanity (Hidayat et al., 2024). When patent law serves only the interests of pharmaceutical capital while ignoring its human consequences, it ceases to be law in the moral sense. For Satjipto, positivist rigidity represents a form of institutional decay: law becomes a structure without soul. His critique demands that legal systems remain dynamic and compassionate, daring enough to challenge structures of domination that perpetuate suffering (Amelia, 2023). In the field of patent law, this translates into a moral duty to ensure that the protection of innovation never eclipses the sanctity of human life.

Barry Mitnick's theory of regulation introduces a complementary yet critical sociological perspective. In The Political Economy of Regulation and Capturing "Capturing", Mitnick argues that regulation often becomes a site of contestation among powerful interests. When private actors manage to steer the regulatory agenda, a phenomenon known as regulatory capture emerges (Mitnick, 2019). In the pharmaceutical domain, capture manifests when patent policy aligns more with the logic of global trade than with the moral imperatives of public health (Babyar, 2023). Mitnick's framework does not reject markets per se; rather, it calls for institutional balance, where the state maintains its capacity to mediate between economic efficiency and social legitimacy. In this sense, a regulatory regime achieves justice not through market autonomy but through institutional reflexivity.

Taken together, the Rawls–Satjipto–Mitnick triad provides a multidimensional framework for reading pharmaceutical patent justice. Justice, in this perspective, is not a formal equilibrium between rights and obligations but a reflective process that evaluates how legal structures create—or fail to create—more humane social conditions. Through this lens, India and Indonesia represent two historical experiments in negotiating the tension between intellectual property and public welfare. India, emerging from postcolonial self-determination, forged a morally assertive legal framework that resisted multinational pharmaceutical dominance. Indonesia, conversely, began on a path of formal compliance with global legal harmonization and only recently has begun to reimagine its patent system in search of substantive fairness.

This comparative inquiry is thus not merely descriptive but normative. It seeks to understand how law can evolve from an instrument of control into an institution of justice. The evolution of pharmaceutical patents, particularly in developing economies, mirrors the moral development of the state itself: from legal formalism toward reflective governance. In both India and Indonesia, the patent system becomes a mirror through which we can read not only the nation's regulatory design but also its ethical imagination—the courage to decide whose life the law ultimately serves.

Studies such as those by Tenni et al. (2022) and Khachigian (2020) systematically review the global evidence on how intellectual property rules affect medicine accessibility, often highlighting the tension between innovation incentives and public health. Concurrently, country-specific analyses like Dash et al.'s (2023) review of the Indian patent system detail the operational mechanisms of national regimes. However, a significant research gap persists: most studies are either purely doctrinal or econometric, lacking a deep philosophical and comparative institutional inquiry that synthesizes normative theories of justice with the political economy of regulation, particularly in a comparative context between major developing nations.

This gap is particularly acute when examining the distinct evolutionary paths of India and Indonesia. India's patent regime, especially its landmark Section 3(d) and the judicial precedent set in the Novartis case, has been extensively documented. In contrast, Indonesia's recent and transformative Law No. 65 of 2024 has yet to be thoroughly analyzed within a robust theoretical framework that can explain its potential shift from legal formalism towards a more justice-oriented model. The urgency of this research is underscored by the ongoing global health crises and the persistent inequities in medicine access, which demand a critical re-evaluation of whether patent systems are structured to fulfill their ultimate social purpose—serving human welfare.

The novelty of this research lies in its unique interdisciplinary approach, integrating three distinct philosophical frameworks to construct a comprehensive analytical lens. It employs John Rawls's theory of distributive justice to evaluate fairness, Satjipto Rahardjo's progressive law to assess the humanistic orientation of legal evolution, and Barry Mitnick's political economy of regulation to diagnose institutional integrity and risks of regulatory capture. This tripartite theoretical synthesis is applied to a systematic comparative analysis of India and Indonesia from 1970 to 2024, tracing their journeys through stages of legal learning—from formalism to moral institutionalism and, potentially, reflexive governance.

The primary purpose of this study is to conduct a comparative philosophical inquiry into the pharmaceutical patent regimes of India and Indonesia. It aims to meticulously trace their historical and institutional evolution to identify the epistemological foundations of their respective approaches to balancing patent rights with public health imperatives. By applying the Rawls-Satjipto-Mitnick triad, the research seeks to diagnose the moral performance of each system and, from this analysis, derive a normative model for just patent governance in developing economies.

The ultimate benefit of this research is the formulation of the Balanced Patent Justice Framework (BPJF), a prescriptive model designed to guide policymakers, legal scholars, and public health advocates. The BPJF provides a structured set of principles for designing patent

systems that are not only TRIPS-compliant but also morally legitimate, institutionally robust, and effectively geared towards improving access to essential medicines for the most disadvantaged populations. This contribution is vital for informing future legal reforms in Indonesia, other ASEAN countries, and the broader global South, advocating for a paradigm where intellectual property law serves as a bridge to health equity rather than a barrier.

METHOD

This study employed a jurisprudential-philosophical framework integrating doctrinal and historical analysis with institutional and sociological inquiry. The approach was grounded in three interlocking theoretical axes: John Rawls's theory of distributive justice, Satjipto Rahardjo's progressive law, and Barry Mitnick's political economy of regulation. Each framework contributed a distinct evaluative lens—Rawls for moral fairness, Satjipto for humanistic transformation, and Mitnick for institutional integrity—enabling a multidimensional reading of pharmaceutical patent regimes as both normative structures and moral economies.

Doctrinal analysis involved close reading of statutory texts, policy instruments, and judicial decisions in India and Indonesia. Key legislations included the Indian Patents Act 1970 with its 2005 amendment introducing Section 3(d), relevant jurisprudence such as Novartis AG v. Union of India (2013), as well as the Indonesian Patent Acts of 2001, 2016, and 2024. The historical dimension situated these legal changes within broader socio-political contexts: India's postcolonial developmentalism and Indonesia's post-reform technocratic modernization, both framed by TRIPS compliance and the global intellectual property regime.

The analytical process applied a process-tracing methodology to identify three stages of legal learning: (1) legal formalism, treating law as a closed system of commands; (2) moral institutionalism, where law embodied values of justice and public welfare; and (3) reflexive governance, in which law became self-corrective through engagement with society. These stages facilitated a comparative temporal mapping of how each country's patent system evolved from a formal to a moral-ethical orientation.

To supplement doctrinal and historical analysis, the study incorporated regulatory institutional analysis following Mitnick's perspective, focusing on the dynamics of capture and counter-capture within pharmaceutical patent governance. Institutional mechanisms such as India's NPPA (National Pharmaceutical Pricing Authority) and Indonesia's digital patent reporting portal from the 2024 reform were interpreted as reflections of the state's moral stance on market power and public health rather than mere administrative tools.

Additionally, descriptive policy simulations illustrated the social implications of legal reform. For example, economic effects of compulsory licensing and the Bolar exception policies were examined using comparative data on drug price elasticity and generic market entry timelines. These simulations served an illustrative function, estimating how normative legal changes might translate into distributive impacts on medicine access.

RESULT AND DISCUSSION

The Evolution of India's Pharmaceutical Patent Regime (1959–2024)

The rise of India's pharmaceutical patent law can be traced to 1959, when the Justice N. R. Ayyangar Report on the Revision of the Patents Law laid the intellectual foundations for one of the most radical legal transformations in the post-colonial world. The report declared that monopolies over vital products such as food and medicines were fundamentally inconsistent with the public interest. Granting exclusive product rights to foreign companies, Ayyangar warned, would perpetuate economic dependence and stifle indigenous innovation. His recommendation—to allow *process* patents but not *product* patents—was adopted in the Patents Act 1970, which explicitly excluded pharmaceutical products from patentability (Dash et al., 2023).

This single legislative decision catalyzed the birth of a robust local pharmaceutical industry grounded in process-engineering expertise. Firms such as Cipla**,** Ranbaxy**,** and Dr. Reddy's Laboratories thrived by reverse-engineering patented molecules and producing affordable generic versions. The outcome was transformative: drugs that cost thousands of dollars in the West were made available in India for less than ten percent of the price. Antibiotics, antiretrovirals, and anticancer agents became accessible not only domestically but also across Africa and Asia. This was more than an economic achievement—it represented a moral breakthrough in legal design.

From a Rawlsian perspective, the 1970 Act embodied the *difference principle* in its most concrete form: limiting exclusive rights so that the benefits of innovation could reach those least advantaged. For Satjipto Rahardjo, it exemplified living law—a legal order that serves life rather than industry. And for Barry Mitnick, it marked a successful episode of *de-capture*, wherein the Indian state reclaimed regulatory autonomy from multinational corporate dominance.

Yet, India's success invited international pressure. After joining the World Trade Organization (WTO) in 1995, the country became bound by the TRIPS Agreement, which mandated twenty-year product patent protection. The Indian government pursued a strategic compromise (Singh et al., 2022). The 1999 amendment introduced a "mailbox" system to accept product patent applications without processing them, thereby buying time for domestic adaptation. The 2002 amendment adjusted patent terms to TRIPS standards but deferred product recognition until 2005, when full compliance became unavoidable.

The 2005 amendment then introduced the now-famous Section 3(d)—the moral centerpiece of India's patent regime. It stipulates that mere new forms of known substances are unpatentable unless they demonstrate *significant enhancement of therapeutic efficacy*. This provision revolutionized global patent jurisprudence by shifting the novelty criterion from chemical formality to clinical benefit. It directly challenged the practice of *evergreening*—where corporations extend monopolies through minor molecular modifications such as salts, polymorphs, or crystalline forms that offer no substantial therapeutic improvement.

The Supreme Court decision in *Novartis AG v. Union of India* (2013) became a landmark in moral jurisprudence. The Court denied Novartis's patent on β-crystalline imatinib mesylate, ruling that it lacked new therapeutic efficacy. The judgment resonated globally as an assertion that law can side with life without suppressing innovation. Scholars have since regarded the case as an

emblem of *substantive justice*—a constitutional moment in which the judiciary reaffirmed the primacy of human welfare over corporate power.

Following 2013, India entered a phase of regulatory consolidation. Administrative reforms—such as streamlining Form 27 and requiring patent holders to report the extent of local working—reflected the Rawlsian notion that rights carry social duties. Patents unused for public benefit lose moral legitimacy. Subsequent reforms in 2020 and 2024 expanded reporting definitions, strengthened transparency, and simplified procedures to encourage compliance.

Institutionally, the Tribunals Reforms Act 2021 abolished the Intellectual Property Appellate Board (IPAB) and transferred appellate jurisdiction directly to the High Courts. This move shortened bureaucratic chains and enhanced judicial accountability. In Mitnickian terms, it represented a *re-institutionalization of independence*—reducing susceptibility to capture by dispersing decision-making across more autonomous judicial bodies.

Equally crucial has been India's commitment to price control through the Drugs (Prices Control) Order (DPCO)**,** implemented by the National Pharmaceutical Pricing Authority (NPPA)**.** The NPPA caps prices for medicines listed in the National List of Essential Medicines (NLEM), ensuring affordability (Sharma et al., 2022). It functions not merely as an economic instrument but as an embodiment of social justice within administrative law. In Satjipto's vocabulary, NPPA demonstrates how law can "live beyond the statute," translating moral intent into economic policy and institutional practice.

Complementing this, the New Drugs and Clinical Trials Rules 2019 (NDCT) tightened standards for new drug approvals and clinical trials, linking patent protection to demonstrable therapeutic value (Singh et al., 2020). Thus, India's patent and health laws interact in a mutually reinforcing system that preserves the moral integrity of pharmaceutical innovation.

Viewed through Rawls's lens, India has successfully constructed a *basic structure* of institutions balancing individual liberty with social justice. Policies fostering generic industries, enforcing price control, and activating compulsory licensing concretize the difference principle by directing material benefits toward the poor. From Satjipto's standpoint, India manifests *progressive law*—a legal order that resists global market dominance and aligns itself with human life. From Mitnick's vantage, the country has maintained *regulatory autonomy* through transparency, pluralism, and judicial vigilance.

In sum, India's experience demonstrates that patent law can serve as a moral institution rather than merely an economic mechanism. It provides empirical proof that a state can use legal power to balance exclusivity and access without undermining innovation. In the global context, the Indian model stands as a living precedent for developing nations seeking to reconcile international obligations with constitutional commitments to human welfare. It shows that the moral imagination of law when coupled with institutional courage can transform intellectual property from a fortress of monopoly into a bridge of justice.

The Evolution of Indonesia's Pharmaceutical Patent Regime (2001–2024)

The trajectory of Indonesia's pharmaceutical patent law emerged from a context markedly different from India's. While India's reform was born out of postcolonial moral defiance and developmental autonomy, Indonesia's evolution unfolded within the technocratic and globalist atmosphere of the post-reform era. The enactment of Law No. 14 of 2001 on Patents marked the first comprehensive attempt to systematize intellectual property within a market-oriented economy (Purwaningsih, 2020). Under the shadow of the recently concluded TRIPS Agreement, Indonesia pledged to fully harmonize its legal framework with international standards, including the recognition of pharmaceutical product patents (Wartini, 2018).

At this early stage, the legal framework was characteristically positivist and formalistic. Its central ambition was not social justice but legal certainty. Parliamentary records and legislative debates reveal that arguments concerning efficiency, investment, and trade liberalization dominated the discourse. In contrast, public health concerns were treated as peripheral consequences to be managed by separate policy instruments. Law, in this period, was viewed as a tool of compliance rather than a matter of conscience. In Satjipto Rahardjo's sense, it was a body without soul—administratively alive yet morally inert.

The reform continued with Law No. 13 of 2016 on Patents, which expanded protection for inventions, reaffirmed the twenty-year exclusivity term, and introduced mechanisms for compulsory licenses, government use, and simple patents. However, the moral logic remained unchanged. The law prioritized predictability and harmonization over substantive equity. Articles 82 to 100 addressed compulsory licensing with careful legal precision but without moral urgency. The provisions were technically sound yet socially sterile: they mentioned public needs abstractly, without embedding the lived realities of medical inaccessibility. The absence of implementation in key pharmaceutical contexts underscored this disjunction between text and life.

From a Rawlsian perspective, such a system embodied formal equality but lacked corrective justice. All actors were treated equally before the law, yet this equality did nothing to rectify structural disparities between multinational pharmaceutical corporations and low-income populations. The law appeared transparent but, in essence, was indifferent to distributional inequities. Its neutrality became a form of neglect.

This problem extended to the so-called working requirement stipulated in Article 20 of the 2016 law, which obliged patent holders to implement their inventions domestically. In practice, however, implementation was narrowly defined as physical production within Indonesia, excluding broader dimensions such as technology transfer, local partnerships, or social benefit. This reductionism transformed a potentially progressive norm into mere bureaucratic formalism. Mitnick would classify this as symbolic compliance: a form of regulatory performance that displays adherence to international norms without substantive social effect.

Institutionally, Indonesia's patent and health regimes remained fragmented. The Ministry of Health lacked authority to determine compulsory licensing policy, while the National Agency for Drug and Food Control (BPOM) was confined to issues of safety and efficacy. The Ministry of Law and Human Rights managed patents as administrative property, detached from the moral imperatives of public health. This compartmentalization rendered patent law normatively

incomplete and ethically unresponsive. Access to essential medicines became contingent on market generosity rather than legal design (Perehudoff, 2020).

A shift began to take form with the promulgation of Law No. 65 of 2024 on Patents. This reform marked a pivotal moment in Indonesia's search for equilibrium between legal certainty and substantive justice. The legislative process reflected an emerging recognition that patent law cannot be isolated from the state's moral responsibility to public health. The academic manuscript and parliamentary minutes reveal a new discourse: law not merely as protection of rights but as an instrument of social balance.

Article 49 of the 2024 law expanded the scope of the Bolar exception, permitting research, bioequivalence testing, and preparation for generic registration even before patent expiration. Though technical in appearance, this change carries profound distributive consequences. It enables domestic pharmaceutical firms to prepare generic dossiers so that production can begin immediately after patent expiry. From a Rawlsian perspective, this reform realizes fair equality of opportunity within the knowledge economy: the chance to participate in innovation and commerce should not be monopolized by a few holders of global patents.

Articles 82 to 88 were reformulated to clarify the grounds and procedures for compulsory licensing. Licenses can now be issued not only in cases of unmet public need but also in situations of health emergencies, unaffordable prices, or absence of domestic production. This broadening translates the difference principle into concrete legal terms: a monopoly may be tolerated only to the extent that it yields social benefit. In Satjipto's language, compulsory licensing becomes the moral face of law—where written norms bow before the primacy of human life.

Articles 100 to 103 on government use were also restructured. The state can now exploit patents without authorization for urgent national purposes, subject to fair compensation. This mechanism serves as a counter-capture tool in Mitnick's sense: it restores the government's capacity to intervene when market mechanisms fail to deliver social goods.

The working requirement under Article 20 was radically expanded. The 2024 law redefined implementation to include not only manufacturing but also technology transfer, human resource development, and partnerships with local firms. Patent rights were thus transformed from mere symbols of ownership into instruments of knowledge distribution. This aligns directly with Rawls's moral logic, which holds that rights are legitimate only when they serve social purposes and uplift the least advantaged.

A significant institutional innovation accompanied these reforms: the introduction of an integrated digital reporting system under the Ministry of Law and Human Rights. Patent holders must now disclose the status of local implementation, technology collaboration, and product availability in the domestic market. This transparency reduces the informational asymmetry that enables capture, reinforcing accountability and public oversight—an embodiment of Mitnick's de-capture architecture.

These legal transformations acquire deeper meaning when viewed against Indonesia's industrial realities. Over the past two decades, the domestic pharmaceutical sector has remained heavily dependent on imported active pharmaceutical ingredients and multinational corporations.

The 2024 reforms open pathways for local capacity building through inclusive legal mechanisms. The expanded Bolar exception, for instance, allows generic laboratories to prepare dossiers up to eighteen months in advance, aligning with BPOM's average registration timeframe. Policy simulations suggest that generic entry within one year of patent expiry could reduce average drug prices by 40–60 percent within two years—figures consistent with India's experience following its 2012 compulsory licensing reform.

The same distributive logic applies to government and compulsory licensing. Comparative models, such as those developed by Watal (2021), indicate that the active use of compulsory licensing in countries like India and Brazil lowers average generic prices by 30–50 percent relative to jurisdictions that rely solely on post-expiry competition. If Indonesia were to implement similar policies for just two or three strategic molecules—such as anticancer or antiretroviral drugs—public expenditure savings could reach hundreds of billions of rupiah annually while stimulating domestic innovation.

Within Satjipto's framework, such policies embody the moral courage of a state that transforms law from a bureaucratic text into a living praxis of emancipation. Law ceases to be a cold instrument of order and becomes a gesture of compassion encoded in institutional form. To legislate in favor of access to medicine is, in this sense, to legislate for life. Law transcends its own textual limits when the sanctity of life demands it. Law No. 65 of 2024 represents an embryonic step toward this paradigm.

Nonetheless, Mitnick's caution remains pertinent: every act of de-capture invites the possibility of re-capture. Global pharmaceutical interests may resort to diplomatic, investment, or arbitration pressures to contest redistributive legal measures. Indonesia must therefore maintain coherence with TRIPS while safeguarding its Rawlsian commitment to protect the least advantaged. Regulatory autonomy will depend not merely on legislative text but on institutional vigilance.

When compared, India and Indonesia illustrate two epistemological paths for understanding the relationship among law, innovation, and justice. India locates patent law within a moral ecosystem of social policy, while Indonesia is gradually moving from formal compliance toward reflective balance. The 2024 reform signals that Indonesia is beginning to perceive law not only as a command but as a conscience. Should implementation remain faithful and inter-ministerial coordination strengthen among the Ministry of Law, the Ministry of Health, and BPOM, Indonesia could transform from a state of compliance to a state of equilibrium from textual positivism to moral reflexivity.

At its deepest level, law is not a system of commands written on parchment but a structure of values animating the ideal of justice. In the realm of pharmaceuticals, this ideal is the right of every human being to live in health and dignity (Hakim et al., 2023; Jawad & Bonny, 2024). Rawls calls this the right to fair opportunities for the means of happiness; Satjipto calls it the right to live within a humane law. Law No. 65 of 2024 represents Indonesia's first conscious effort to return patent law to its moral vocation the vocation to protect life rather than merely to regulate commerce.

Comparative Analysis and Theoretical Discussion: Rawls–Satjipto–Mitnick

The comparative evolution of pharmaceutical patent regimes in India and Indonesia reveals two distinct epistemological trajectories in the relationship between law, innovation, and justice. India conceptualizes law as an integral part of moral governance—embedded in a reflexive network of social and institutional feedback—while Indonesia is only beginning to transcend its formalist and technocratic orientation toward a more human-centered and justice-oriented model. Both countries operate within the constraints of globalization and TRIPS compliance, yet they differ fundamentally in how they interpret the moral and institutional purpose of law itself.

In India, patent regulation has never existed in isolation. It has always been intertwined with larger political and developmental objectives: national self-reliance, industrial capacity building, and public health protection. This pluralistic coordination among ministries—the Ministry of Commerce and Industry, the Ministry of Health, and an independent judiciary—produces a balanced form of governance where patent control, price regulation, and clinical safety intersect. In Mitnick's terms, this represents an ideal form of shared regulation: regulatory authority is distributed to prevent capture, and institutional pluralism sustains both efficiency and legitimacy.

Indonesia, by contrast, historically relied on centralized administration under the Ministry of Law and Human Rights, treating patents primarily as legal-technical property rather than instruments of social justice. The Ministry of Health and BPOM were structurally detached from the domain of intellectual property, leading to fragmentation and policy dissonance. Law functioned as a compliance mechanism, not a moral compass. The 2024 reform begins to challenge this model by introducing inter-ministerial integration through digital transparency systems and substantive working requirements that mandate technology partnerships. This signals a potential shift from administrative isolation to institutional interdependence—a hallmark of reflexive governance.

Through process tracing, both countries exhibit parallel yet asynchronous stages of legal learning. The first stage, legal formalism, treats law as a closed normative order—observable in India before 1970 and in Indonesia before 2016. The second stage, moral institutionalism, emerges when law begins to embody social justice values: India entered this phase with the 2005 amendment introducing Section 3(d), while Indonesia entered it with the 2024 reform expanding compulsory licensing and Bolar exception. The third stage, reflexive governance, is reached when law becomes evaluative and self-corrective, assessing its own social outcomes rather than merely ensuring procedural validity. India has already moved into this stage, integrating judicial oversight, price regulation, and transparency mechanisms. Indonesia is just entering the threshold, but the direction is promising.

Policy simulations underscore the material significance of these normative shifts. As Watal's 2021 study demonstrates, India's active use of compulsory licensing in 2012 reduced the average price of anticancer drugs by nearly 87 percent. The cost of sorafenib tosylate dropped from roughly USD 5,600 per month to USD 175, granting thousands of patients access to previously

unaffordable treatments. If Indonesia were to apply its new 2024 mechanisms to even two priority molecules—such as lung and leukemia therapies—the potential fiscal savings could reach hundreds of billions of rupiah annually, while simultaneously stimulating domestic manufacturing capacity. Yet, as Rawls reminds us, the moral measure of law lies not only in numbers but in the ethical structure of institutions. A just patent regime must cultivate a social ethos that values human life as the ultimate beneficiary of innovation.

In Rawlsian terms, both systems can be interpreted as evolving structures of fairness. India exemplifies a mature application of the difference principle, where patent privileges are justified only insofar as they yield tangible improvements for the least advantaged. Its institutions—NPPA, compulsory licensing authorities, and judicial review—act as distributive correctives. Indonesia, on the other hand, is still negotiating between formal equality and substantive fairness. The 2024 reform marks its first genuine attempt to embed corrective justice within its patent structure, redefining the moral boundaries of exclusivity through conditions of affordability, emergency, and technology transfer.

From Satjipto Rahardjo's standpoint, the two trajectories represent different degrees of legal humanization. India's law has evolved into a living system that continuously aligns itself with the demands of life; it is a form of progressive jurisprudence that refuses to remain captive to textual rigidity or global market orthodoxy. Indonesia is in the early stages of such a transformation. The 2024 reform introduces empathy into the legal framework, as evidenced by provisions that prioritize public welfare over mere compliance. When patent clauses begin to embody compassion, when legal texts are written with the consciousness of human suffering, law begins to regain its soul.

From Mitnick's analytical lens, these developments can be read as dynamic contests between capture and counter-capture. India's design disperses regulatory authority, preventing domination by any single interest. The NPPA and High Courts act as institutional counterweights to corporate power. Indonesia's reforms, particularly the digital transparency requirement and inter-agency coordination, represent nascent attempts to institutionalize counter-capture mechanisms. Nevertheless, vulnerability remains high: external pressures from trade diplomacy and investor-state dispute mechanisms can easily threaten regulatory independence. Sustaining autonomy will require continuous political will and epistemic coherence among institutions.

Doctrinally, the comparison highlights critical differences in substantive law. India's Section 3(d) acts as a moral filter, denying patents that fail to produce a genuine therapeutic benefit. Indonesia still lacks such a provision, but compensates through expanded exceptions and licensing mechanisms. India's active jurisprudence in public interest litigation contrasts with Indonesia's nascent judicial engagement, which remains largely administrative. Yet both nations share an emerging awareness that intellectual property cannot be ethically neutral. The legitimacy of patent law must rest on its moral performance—its ability to protect both innovation and life.

The philosophical synthesis of Rawls, Satjipto, and Mitnick thus provides a triadic framework for interpreting these trajectories. Rawls contributes the principle of distributive fairness—law must equalize not only opportunity but also outcomes for the disadvantaged. Satjipto

introduces the principle of humanistic teleology—law exists to serve life, and legal evolution must reflect moral progress. Mitnick provides the institutional realist lens—justice requires robust governance structures capable of resisting capture and ensuring accountability. Together, these frameworks outline a comprehensive moral-institutional theory of patent justice.

The comparative lesson is clear: formal compliance with global norms is not synonymous with justice. Law achieves legitimacy only when it resonates with the ethical conscience of its society. India's journey illustrates the moral maturity of a state that dares to reinterpret international obligations through the lens of human dignity. Indonesia's reform demonstrates the awakening of a legal consciousness that recognizes compliance as the beginning, not the end, of justice. Between them lies a shared aspiration: to construct a patent regime that transforms knowledge into a social good rather than a private fortress.

In this sense, the philosophical debate over patents is no longer about ownership but about moral architecture. Patent law becomes a mirror of how a nation understands the meaning of progress whether as accumulation or as emancipation. The Rawls–Satjipto–Mitnick synthesis invites both countries, and indeed the global community, to view law not merely as a tool for regulating innovation but as a living covenant between the state and humanity a covenant in which the advancement of science finds its purpose in the flourishing of life itself.

Balanced Patent Justice Framework (BPJF)

The comparative trajectories of India and Indonesia demonstrate that the pursuit of justice in pharmaceutical patent law cannot be reduced to a balance between innovation and access. What is required is a holistic normative model capable of harmonizing three moral imperatives: distributive fairness, humanistic purpose, and institutional integrity. The Balanced Patent Justice Framework (BPJF) proposed in this study integrates these imperatives into a coherent structure, offering a conceptual blueprint for reforming patent regimes in developing economies facing the dual challenge of compliance and conscience.

The BPJF rests upon three foundational pillars. The first is Rawlsian distributive fairness, which anchors the ethical justification of patent rights in their capacity to improve the conditions of the least advantaged. The second is Satjipto Rahardjo's principle of humanistic law, which demands that legal institutions continuously evolve to serve life rather than merely preserve order. The third is Barry Mitnick's institutional realism, which recognizes that justice cannot survive in captured systems; it requires governance architectures that are reflexive, transparent, and resistant to domination. These three elements—fairness, humanity, and autonomy—constitute the moral geometry of the BPJF.

Under this framework, patent law is reconceptualized not as a static property regime but as a dynamic moral institution. Each element of the patent system—substantive standards, procedural mechanisms, and institutional arrangements—must operate within the triadic balance of justice, humanism, and integrity. Substantively, this means evaluating patents not merely by novelty or inventive step but by their demonstrable therapeutic and social utility. A patent that produces no tangible improvement in public welfare, even if technically innovative, lacks moral justification.

Procedurally, the BPJF requires that decision-making processes incorporate social impact assessments and participatory review mechanisms involving civil society, academia, and public health agencies. Institutionally, it calls for distributed governance models in which multiple bodies share oversight, thereby preventing monopolization of authority and mitigating capture.

In practical terms, the BPJF translates into a system of collaborative governance among key state actors. The Ministry of Law and Human Rights functions as the administrative guardian of patent registration and enforcement. The Ministry of Health assumes the role of moral arbiter, ensuring that patents align with public health objectives. The National Agency for Drug and Food Control (BPOM) provides the scientific backbone, linking therapeutic efficacy with legal validity. The National Development Planning Agency (Bappenas) serves as the policy integrator, aligning patent governance with long-term industrial and health development goals. Together, these institutions form a regulatory ecosystem that shifts from a linear to a reflexive model of governance—one in which the value of a patent is judged not only by its compliance with law but by its contribution to life.

The framework's normative operation depends on measurable performance indicators. Justice is assessed through distributive metrics such as the median reduction in essential drug prices within three years of reform, or the proportion of affordable generics available in regions with high poverty indices. Humanity is gauged by qualitative indicators—patient accessibility, social perception of fairness, and the integration of ethical review into patent examination. Institutional integrity is measured by the degree of transparency in reporting, the independence of regulatory decisions, and the state's capacity to resist external or corporate pressures. These indicators form an evaluative triad that enables continuous moral auditing of the patent system.

The BPJF also envisions public interest jurisprudence as a vehicle for moral learning. Strategic litigation by universities, patient organizations, and legal aid institutes can help generate a body of case law that interprets patents through the lens of distributive and humanistic justice. Courts, in this view, become moral laboratories—forums where law tests its own conscience. Over time, such jurisprudence can cultivate a legal culture that views access to medicine as a fundamental expression of the right to life rather than a derivative of market privilege. This aligns with Satjipto's vision of living law, where judicial interpretation becomes a continuation of social ethics rather than an exercise in textual exegesis.

Equally central to the BPJF is the principle of reflexivity. Institutions must not only act but also reflect upon their actions. Annual reviews involving independent academic panels and public consultations can serve as feedback loops, allowing the patent system to recalibrate its norms through empirical and ethical evaluation. This reflexive design draws on Mitnick's insight that institutions must internalize mechanisms of counter-capture—structures that compel them to justify decisions in light of both efficiency and legitimacy. Such self-critical governance ensures that law remains open to moral correction, a hallmark of progressive legal evolution.

Applied to Indonesia, the BPJF suggests several structural reforms beyond the 2024 Patent Law. First, the establishment of a Patent Impact Assessment Unit under joint oversight of the Ministry of Health and the Ministry of Law, tasked with evaluating the public welfare implications

of major patents. Second, the institutionalization of a digital transparency platform that discloses patent implementation data, licensing terms, and price outcomes to the public. Third, the inclusion of a substantive therapeutic-benefit clause—analogous to India's Section 3(d)—to filter out non-innovative patents that contribute little to clinical progress. Fourth, the creation of an inter-ministerial patent ethics council, functioning as a moral deliberative body capable of advising the government in cases of conflicting interests between industry and public health. These reforms would operationalize the moral architecture envisioned by the BPJF.

From a broader perspective, the BPJF redefines the philosophical meaning of intellectual property. It posits that ownership of knowledge carries inherent obligations to share, that innovation entails social stewardship, and that the legitimacy of rights depends on their contribution to collective flourishing. Rawls would describe this as transforming the basic structure of society to reflect fairness as a lived reality. Satjipto would call it a humanization of law—law that breathes with compassion. Mitnick would see it as the institutionalization of integrity—an administrative design that guards morality against the corruption of power.

In essence, the Balanced Patent Justice Framework is not merely an academic abstraction but a moral proposal for legal design. It invites lawmakers, regulators, and scholars to reconceive intellectual property as a covenant between creativity and humanity. By embedding justice, empathy, and accountability into the very machinery of law, BPJF aspires to reconcile the ethics of invention with the ethics of care. A patent system designed under this philosophy does not measure success by the number of patents granted or investments attracted, but by the lives improved and the trust restored in law as a guardian of human dignity.

Ultimately, the BPJF envisions a transformation of legal consciousness: from law as authority to law as integrity, from innovation as profit to innovation as participation, from exclusivity as privilege to exclusivity as responsibility. In the evolving moral landscape of global health governance, such a framework offers not only a pathway for Indonesia and India but also a template for all societies seeking to align technological progress with the enduring imperative of justice.

CONCLUSION

The evolution of pharmaceutical patent law in India and Indonesia illustrates that law is a dynamic moral organism evolving alongside society's ethical consciousness. India's patent regime, grounded in social welfare and transparency, has long prioritized public health over corporate interests, demonstrating that developing nations can align innovation with justice. Indonesia's 2024 Patent Law reform marks its shift toward this moral trajectory by embracing reflective equilibrium beyond formal compliance. Viewed through Rawls's concept of justice as fairness, Satjipto Rahardjo's living law, and Barry Mitnick's regulatory balance, this evolution reflects a profound recalibration where law becomes a compassionate, self-corrective institution committed to reducing medicine prices, expanding access, and restoring public trust. Both countries exemplify that justice in patent law transcends quantitative measures, focusing instead on moral outcomes that dignify patients and empower the state as a guardian of life. Future

research could explore how the Balanced Patent Justice Framework can be operationalized across diverse developing contexts, assessing its impact on aligning legal norms with ethical governance and public health outcomes.

REFERENCE

Amelia, S. (2023). Progressive Legal Approach to Modern Community Law Enforcement in Indonesia. *Pancasila and Law Review*, *4*(1), 1-12. https://doi.org/10.25041/plr.v4i1.2729

Babyar, J. (2023). Trade, intellectual property, and the public health bearing. *Health Systems*, *12*(1), 123-132. https://doi.org/10.1080/20476965.2022.2062460

Dash, D. K., Vaiswade, R., & Gupta, G. (2023). A review on the Indian Patent System and its implication on the pharmaceutical industry. *Journal of Health Science and Medical Research*, *41*(3), 2023926. http://dx.doi.org/10.31584/jhsmr.2023926

Hakim, A. L., Prasetyawan, F., Saristiana, Y., Muslikh, F. A., Dhafin, A. A., Mildawati, R., ... & Rofiq, A. (2023). Pharmacy Philosophy in the Law of Power: The Morality of Pharmaceutical Ethics towards Rhetoric of Logic. *International Journal of Contemporary Sciences (IJCS)*, *1*(2), 67-76.

Hidayat, M. R., Suteki, S., & Mahoro, J. C. G. (2024). Legal Wisdom in Indonesian Legal System: Toward Progressive Law Enforcement. *JUSTISI*, *10*(3), 518-534. https://doi.org/10.33506/js.v10i3.3198

Jawad, A. M., & Bonny, I. (2024). Patent Injustice and Right to Health. *Journal of Medicine, Nursing and Public health*, *4*(1), 17-36.

Khachigian, L. M. (2020). Pharmaceutical patents: reconciling the human right to health with the incentive to invent. *Drug discovery today*, *25*(7), 1135-1141. https://doi.org/10.1016/j.drudis.2020.04.009

Mitnick, B. M. (2019). Origin of the theory of agency: an account by one of the theory's originators. *Available at SSRN 1020378*. http://dx.doi.org/10.2139/ssrn.1020378

Muis, L. S., Jened, R., Barizah, N., & Mediawati, N. F. (2025). Patent protection legal facility for access and availability of pharmaceutical products. *BIS Humanities and Social Science*, *3*, V325024-V325024. https://doi.org/10.31603/bishss.417

Orji, C. P., Nwagbara, R. G., Egberongbe, T. T., & Chukwu, P. D. E. (2025). A Critique of John Rawls Ethical Principle of Justice and the Problems of Social Justice in Modern Society. *NIU Journal of Legal Studies*, *11*(1), 73-80. https://doi.org/10.58709/niujls.v11i1.2136

Paes, T. D., Aguiar, L. F., & Martins, T. D. (2020). Identification of US-pharmaceutical patents expiring between 2018 and 2022 and their effect on the Brazilian domestic market. *World Patent Information*, *63*, 101999. https://doi.org/10.1016/j.wpi.2020.101999

Perehudoff, K. (2020). Universal access to essential medicines as part of the right to health: a cross-national comparison of national laws, medicines policies, and health system indicators. *Global Health Action*, *13*(1), 1699342. https://doi.org/10.1080/16549716.2019.1699342

Premchand, L. (2017). Social Justice and Rawls' Difference Principle. *Essex Student Journal*, *9*(1). https://doi.org/10.5526/esj17

Purwaningsih, E. (2020). Patent Law and Its Enforcement in Indonesia, Japan and the USA. *Jurnal Media Hukum*, 1-22. https://doi.org/10.18196/jmh.20200138

Suryahartati, D., Windarto, W., Nuriyatman, E., & binti Ab Kadir, N. A. (2024). The patent rights of pharmaceutical products and death: between economic balance and human rights. *Legality: Jurnal Ilmiah Hukum*, *32*(2), 330-347. https://doi.org/10.22219/ljih.v32i2.35226

Tenni, B., Moir, H. V., Townsend, B., Kilic, B., Farrell, A. M., Keegel, T., & Gleeson, D. (2022). What is the impact of intellectual property rules on access to medicines? A systematic review. *Globalization and health*, *18*(1), 40. https://doi.org/10.1186/s12992-022-00826-4

Sharma, B., Mehta, A., Farooqui, H. H., Negandhi, H., & Selvaraj, S. (2022). Impact of the drug prices control order (2013) on the utilization of anticancer medicines in India: An interrupted time-series analysis. *Cureus*, *14*(6). https://doi.org/10.7759/cureus.26367

Singh, B., Shastri, A., Mukherjee, B. N., Chutia, U., & Dutta, G. (2022). The Effect of TRIPS Implementation on Indian Patent Law: A Pharmaceutical Industry Perspective: With Special Reference to Healthcare Industry. *Journal of Pharmaceutical Negative Results*, *13*.

Singh, N., Madkaikar, N. J., Gokhale, P. M., & Parmar, D. V. (2020). New drugs and clinical trials rules 2019: Changes in responsibilities of the ethics committee. *Perspectives in clinical research*, *11*(1), 37-43. https://doi.org/10.4103/picr.PICR_208_19

Wartini, S. (2018). The Legal Implication of Compulsory Licence Pharmaceutical Products in the TRIPS Agreement to the Protection of the Right to Health in Developing Countries. *Jurnal Dinamika Hukum*, *18*(1), 1-11.