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Overlapping Intellectual Property Regimes in the Pharmaceutical and Medical Device Sector: Regulatory Gaps, Tension Analysis, and a Harmonized Legal Protection Framework for Indonesia

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ABSTRACT

Background: Pharmaceutical and medical device innovations in Indonesia often generate intellectual outputs eligible for overlapping protection under copyright, patent, and trade secret regimes. These inter-regime overlaps create regulatory gaps, enable cumulative exclusivity, and raise concerns regarding equitable access to health technologies. **Objective:** This study analyzes Indonesia's intellectual property (IP) regulatory framework, identifies structural patterns of overlap across IP regimes, examines key legal tensions affecting public health access, and proposes a harmonized regulatory approach. **Methods:** A normative juridical method was employed, combining statutory analysis, conceptual legal interpretation, and comparative law. Primary materials include Indonesian IP laws and international instruments such as the TRIPS Agreement and the Doha Declaration. Case-based insights were drawn from selected examples in India, Brazil, and the European Union to contextualize regulatory approaches. **Results:** Four typologies of inter-regime overlap were identified, each associated with distinct public health implications. Two critical tensions emerged: (1) trade secret protection limiting the practical effectiveness of compulsory licensing mechanisms, and (2) copyright claims restricting access to safety-related regulatory data. Comparative analysis indicates that while existing regulatory models address specific dimensions of overlap, none provides a fully integrated coordination mechanism. In response, this study proposes a five-principle harmonized framework supported by an operational decision pathway. **Conclusion:** IP overlap represents a structural regulatory challenge in Indonesia's health sector. Addressing this requires coordinated legal reform, strengthened institutional alignment, and clearer implementation mechanisms to balance innovation incentives with public health access.

Highlights:

- Trade secret protection of manufacturing processes structurally nullifies compulsory licensing of product patents — a critical regulatory gap in Indonesia's TRIPS flexibility architecture.
- An operationalized five-principle framework and semi-operational regulatory decision tree are proposed for implementation by DJKI, Kemenkes, BPOM, and KPPU.
- Findings are directly applicable to other lower-middle-income countries navigating IP–health access tensions within the TRIPS framework.

INTRODUCTION

The intersection of intellectual property (IP) law and public health governance represents one of the most consequential regulatory challenges in contemporary health systems, particularly in balancing incentives for innovation with equitable access to essential health technologies.[1,2] In the pharmaceutical and medical device sector, IP protection simultaneously incentivizes innovation while shaping the conditions under which such technologies become accessible to populations in need.[1,3] When multiple IP regimes apply to a single product—as is structurally characteristic of complex pharmaceutical and medical device innovation—the cumulative exclusivity may extend beyond what any single regime originally intended, a phenomenon associated with overlapping protections and strategic patenting practices.[4,5]

Indonesia, as Southeast Asia's largest pharmaceutical market and a country with constitutional obligations to guarantee equitable access to health services, faces significant regulatory challenges at the intersection of intellectual property (IP) law and public health governance.[6,7] The national IP architecture — comprising the Copyright Act (Law No. 28/2014), Trade Secret Act (Law No. 30/2000), and Patent Act (Law No. 13/2016, amended by Law No. 65/2024) — was developed incrementally without a unified cross-regime coordination framework.[8-12] The resulting regulatory fragmentation produces 'IP overlap' conditions: circumstances in which the same intellectual object, product component, or technical document attracts simultaneous or strategic alternating protection under multiple IP regimes.[4,5,12]

Prior studies have examined Indonesia's IP regimes in isolation, without systematically mapping their intersections or analyzing the public health consequences of unregulated overlap.[1,3,12] This study addresses that gap through four analytical contributions: (1) a typological mapping of inter-regime IP overlap in Indonesia's pharmaceutical and medical device sector; (2) a tension analysis of the two most acute conflict points — the patent–trade secret compulsory licensing conflict and the copyright–safety data access conflict; (3) a comparative case-based analysis of regulatory responses in India, Brazil, and the European Union; and (4) an operationalized five-principle harmonized framework with a semi-operational decision tree for regulatory application. These contributions are grounded in Indonesia's TRIPS obligations, the Doha Declaration on TRIPS and Public Health (2001), and the public health access mandate of Law No. 17/2023.[2,6]

METHODS

Research Design

A normative juridical research design was employed, appropriate for systematic analysis of legal texts, doctrines, and the normative architecture governing IP protection.[13] Three complementary approaches were applied: statutory analysis of primary legal materials; conceptual legal analysis to construct the typological and tension analysis framework; and comparative law analysis using documented case outcomes from India, Brazil, and the EU to ground comparative recommendations in concrete regulatory evidence.[13-17] To ensure methodological coherence across legal traditions, comparative findings from Common Law and civil law-influenced systems were translated into principle-based mechanisms—emphasizing functional equivalence (e.g., anti-evergreening, joint examination, competition law enforcement)—to enable their adaptation as regulatory design options within Indonesia's Civil Law framework.

Legal Materials

Primary legal materials comprised: (i) Law No. 28/2014 on Copyright; (ii) Law No. 30/2000 on Trade Secrets; (iii) Law No. 13/2016 on Patents as amended by Law No. 65/2024; (iv) Law No. 17/2023 on Health; (v) the TRIPS Agreement (WTO, 1994); and (vi) the Doha Declaration on TRIPS and Public Health (WTO Ministerial Conference, November 2001).[2,6,8-11] Secondary legal materials included international and comparative pharmaceutical IP scholarship, health law doctrine, and official documentation of the three comparative cases analyzed.[1,3-5,14-17] Case selection criteria: documented regulatory outcomes relevant to at least one of the four overlap typologies; decided by a national court, regulatory authority, or WTO panel; and published in peer-reviewed legal or health policy literature.[14-17]

Analytical Approach

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Statutory analysis identified the object scope, duration, enforcement mechanisms, and TRIPS flexibility provisions of each IP regime[1,2,9,11]. Typological analysis constructed a four-category framework of inter-regime overlap through application of core IP law doctrine: the idea-expression dichotomy (copyright), the public disclosure requirement (patent), and the confidentiality criterion (trade secret).[5,18] Tension analysis applied conflict-of-norms methodology to identify irreconcilable normative demands arising from simultaneous application of two IP regimes to the same object.[1,12] Comparative analysis examined how three jurisdictions operationalized regulatory responses to analogous overlap challenges, with attention to legislative mechanism, institutional architecture, and documented public health outcome.[14-17] The five-principle framework was constructed prescriptively from this analysis and operationalized through a semi-operational decision tree designed for regulatory application by Indonesian IP and health authorities.[12,13]

Ethical Considerations

This study is a normative juridical analysis based exclusively on publicly available legal texts, statutes, judicial decisions, and published academic sources. No human subjects, patient data, or personal information were involved. Institutional ethics review was not required.

RESULTS

Regulatory Architecture

Copyright

Law No. 28/2014 establishes copyright as a declarative, automatic right protecting original expressions. The idea-expression dichotomy is foundational: the law protects the concrete form of expression, not underlying ideas, formulas, or technical concepts.[8] In pharmaceutical and medical device contexts, protectable objects include product manuals, operational guides, labels, scientific promotional materials, software, databases, and technical documentation. The long duration of protection (author's lifetime plus 70 years) creates a structural risk of documentation monopoly when copyright claims extend to technical materials that overlap with trade secret or patent-protected content.

Patent

Law No. 13/2016 as amended by Law No. 65/2024 governs patent protection for technological inventions meeting novelty, inventive step, and industrial applicability criteria. The patent's public disclosure requirement — the social contract of the patent system — mandates full invention disclosure in exchange for time-limited exclusivity.[9,10] Indonesia's patent law incorporates key TRIPS flexibilities: compulsory licensing (Articles 82–90), government use provisions, the Bolar exception for generic drug research, and parallel importation.[2,9,19] The 2024 amendment strengthened compulsory licensing provisions. However, their effectiveness may be constrained in practice when essential manufacturing know-how is retained as a trade secret rather than disclosed in the patent specification, thereby rendering compulsory licensing formally available but operationally limited—a challenge also observed in pharmaceutical patent systems in other jurisdictions.[4,5,11,20]

Trade Secret

Law No. 30/2000 protects commercially valuable confidential information maintained through active secrecy measures, without registration or fixed duration.[11,18] In pharmaceutical companies, trade secret protection is routinely applied to formulations, manufacturing process parameters, clinical data packages, and quality control methods.[5,18] The absence of any public disclosure obligation creates the structural conditions for Type 2 overlap: a rights holder can simultaneously hold a product patent (publicly disclosed) and a trade secret over the manufacturing process necessary to produce the patented product — a combination that may neutralize compulsory licensing effectiveness.[4,20]

TRIPS and Doha Declaration

Indonesia's domestic IP framework operates within the TRIPS Agreement's constraints and flexibilities.[1,2] The Doha Declaration (2001), Paragraph 4, affirms that TRIPS 'can and 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.'[2,21] The Declaration explicitly authorized developing countries to utilize TRIPS flexibilities including compulsory licensing without technology field restrictions.[2,20]

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Indonesia's domestic law formally incorporates these flexibilities, but their operationalization within the specific context of multi-regime IP overlap remains critically underdeveloped, as demonstrated in the tension analysis below.[4,9,11]

Table 1. Comparative regulatory overview of copyright, patent, and trade secret regimes in Indonesia's pharmaceutical and medical device sector

Dimension	Copyright (Law 28/2014)	Patent (Law 13/2016 amd. 65/2024)	Trade Secret (Law 30/2000)
Protected object	Expressed works (written, digital, artistic, software)	Technological inventions: novelty, inventive step, industrial applicability	Non-public information with economic value, maintained in confidence
Protection basis	Automatic upon creation (declarative)	State grant upon examination and registration	Automatic upon secrecy maintenance (no registration required)
Public disclosure	Not required	Required — full disclosure in application	Prohibited — disclosure terminates protection
Duration	Author lifetime + 70 yrs; 50 yrs (institutional)	20 yrs (standard); 10 yrs (simple patent)	Indefinite (contingent on secrecy maintenance)
Key pharma/meddev objects	Manuals, labels, software, databases, trial documentation	Drug compound, device mechanism, process, method	Formulas, process parameters, clinical data, business strategies
TRIPS flexibility available	Fair use; education exception	Compulsory license; parallel importation; Bolar exception	Reverse engineering permissible
Primary public health risk	Restricts access to educational/safety information	Delays generic entry; enables evergreening	Blocks technology transfer; impedes compulsory licensing operability

CL = Compulsory License; UI = User Interface; TRIPS = Agreement on Trade-Related Aspects of Intellectual Property Rights.

Typological Mapping of Inter-Regime IP Overlap

Table 2 presents the four structural typologies of inter-regime IP overlap identified in Indonesia's pharmaceutical and medical device sector, each with its mechanism, sectoral examples, and public health risk level.

Table 2. Typological mapping of inter-regime intellectual property overlap: mechanisms, examples, and public health risk profiles

Typology	Overlap Mechanism	Pharmaceutical Example	Medical Device Example	Public Health Risk Level
T1: Copyright–Trade Secret	Technical document is simultaneously a copyrightable work and contains protected	Drug formulation protocol: copyrighted	Device calibration SOP: copyrighted manual + proprietary process	Moderate — restricts regulatory access to safety documentation

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	confidential information	document + trade secret data		
T2: Patent–Trade Secret (strategic alternation)	Rights holder foregoes patent to preserve trade secret status; product patent exists but manufacturing know-how is withheld as trade secret	Manufacturing process: trade secret prevents operability of product patent compulsory license	Sensor algorithm: not patented to retain indefinite secrecy and avoid CL exposure	High — structurally nullifies compulsory licensing for domestic manufacturing
T3: Patent–Copyright (documentation + software)	Technological invention documented through, or embedded within, copyrightable works; device software extends exclusivity	Drug clinical documentation: patent on compound + copyright on trial reports	Medical device: patent on mechanism + copyright on embedded software and UI	High — software copyright extends effective exclusivity beyond 20-year patent term
T4: Triple-regime overlap	Simultaneous coexistence of all three regimes across different product components in one innovation cycle	Novel drug: patent (compound) + copyright (clinical documentation) + trade secret (unpublished formulation data)	Diagnostic device: patent (core mechanism) + copyright (software) + trade secret (calibration parameters)	Critical — maximum exclusivity accumulation; greatest barrier to generic/copy-device entry

T1–T4 = Overlap typology categories; CL = Compulsory License; SOP = Standard Operating Procedure; UI = User Interface.

Tension Analysis: Two Critical Inter-Regime Conflict Points

Tension analysis identifies circumstances in which two IP regimes simultaneously apply to the same object and generate irreconcilable normative demands — conditions that cannot be resolved by applying both regimes in parallel. Two conflict points are critical in Indonesia's pharmaceutical and medical device sector.

Tension 1: Patent–Trade Secret in Compulsory Licensing

Compulsory licensing under Article 82 of Indonesia's Patent Act authorizes the government or a third party to use a patented invention without the rights holder's consent in defined circumstances, including national emergency, public interest, and anti-competitive conduct. The TRIPS Agreement (Article 31) and the Doha Declaration formally endorse this mechanism as a legitimate public health tool.

The critical tension arises when the manufacturing process necessary to produce the patented product is maintained as a trade secret. A compulsory license grants the licensee the legal right to produce the patented compound or device — but the technical knowledge required to manufacture it may remain protected as a trade secret, to which the compulsory license does not extend. This normative gap is not merely theoretical: trade secret law's indefinite, disclosure-free protection structure is directly

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incompatible with the compulsory licensing mechanism's premise that a license provides sufficient access to actually manufacture the product.

The tension structure can be stated as a formal conflict: Patent law (via TRIPS Art. 31 and Patent Act Art. 82) requires that compulsory license access be sufficient to enable effective working of the patent. Trade secret law (Law No. 30/2000) provides indefinite protection for process information without any compulsory disclosure mechanism. When these two rights coexist in the same product system, the compulsory license is legally available but practically inoperable — a condition that may systematically nullify Indonesia's TRIPS flexibility commitments for pharmaceutical manufacturing. Resolution requires either a legislative provision mandating trade secret disclosure as a condition of product patent registration, or a judicial doctrine treating process trade secrecy as an anti-competitive barrier to compulsory licensing operability.

Tension 2: Copyright–Trade Secret in Regulatory Safety Data Access

The second critical tension involves the simultaneous application of copyright and trade secret protection to technical documentation submitted to BPOM for pharmaceutical and medical device regulatory approval. Regulatory submissions — including clinical trial reports, product specifications, manufacturing process documentation, and bioequivalence data — are required by law for market authorization. These documents are simultaneously: (a) copyrightable works under Law No. 28/2014 (as original technical writing); and (b) trade secrets under Law No. 30/2000 (as proprietary data packages with economic value, maintained in confidence).

The tension arises when a generic manufacturer or a regulatory authority seeks access to previously submitted safety and efficacy data. Data exclusivity provisions in Indonesia's patent law create a time-limited window during which BPOM may not rely on originator data for generic registration — a legitimate regulatory protection. However, when copyright and trade secret claims are stacked on top of data exclusivity, the rights holder may invoke these protections to obstruct data access even after the data exclusivity period expires. Copyright's long duration (50+ years for institutional works) creates a particularly acute conflict: safety-relevant data that society has a legitimate interest in accessing may be locked behind copyright claims long after any reasonable innovation incentive justification has expired. This tension directly impedes BPOM's regulatory capacity and can delay generic product approvals with consequences for essential medicine access.

Case-Based Comparative Analysis

Three documented cases from India, Brazil, and the European Union illustrate how analogous IP overlap challenges have been resolved through concrete regulatory mechanisms. Each case is analyzed for its mechanism, decision, and implication for Indonesia's regulatory reform.

Case 1: Novartis AG v. Union of India (India, Supreme Court, 2013)

Case facts and decision

Novartis AG applied for a patent in India for the beta-crystalline form of imatinib mesylate (Gleevec/Glivec), a chronic myeloid leukemia treatment. The Madras Patent Office rejected the application on the basis of Section 3(d) of India's Patents Act, which excludes from patentability '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.' The Supreme Court upheld the rejection in 2013, finding that Novartis had not demonstrated enhanced therapeutic efficacy over the previously known imatinib mesylate form. The case directly addressed a Type 4 overlap scenario: Novartis simultaneously maintained trade secret protection over manufacturing process parameters, copyright over clinical documentation, and sought patent protection over the new crystalline form. The Supreme Court's decision effectively prevented the patent component of this triple-regime structure from being established, reducing the overlap to copyright and trade secret components that carry substantially lower public health risk.

Mechanism and Indonesian implication

Section 3(d) functions as an explicit anti-evergreening provision that addresses both the substantive patent eligibility standard and, indirectly, the patent–trade secret overlap dynamic: by restricting patents to genuinely inventive incremental innovations, it reduces the field over which patent–trade secret strategic alternation can be exercised. Indonesia's current patent law does not contain a directly

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equivalent provision, though the 2024 amendment introduced additional specificity for pharmaceutical patent eligibility. A Section 3(d)-equivalent provision in Indonesia's Patent Act would partially address Type 2 and Type 4 overlap by narrowing the range of pharmaceutical innovations for which the patent–trade secret alternation strategy is available, reducing the population of cases in which trade secrecy can be used to nullify compulsory licensing.

Case 2: Brazilian Efavirenz Compulsory License (Brazil, Ministry of Health, 2007)

Case facts and decision

In May 2007, Brazil's Ministry of Health issued a compulsory license for efavirenz (an antiretroviral used in HIV/AIDS treatment), invoking the 'public interest' ground under Brazilian industrial property law and TRIPS Article 31. The license was issued against Merck & Co. after negotiations over pricing failed. Brazil then imported generic efavirenz from Thailand — which had issued its own compulsory license — and later arranged domestic generic production through Farmanguinhos, the state pharmaceutical laboratory.

The case is directly relevant to Indonesia's Type 2 overlap tension (patent–trade secret in compulsory licensing). Brazil's effective exercise of its compulsory license succeeded because the generic manufacturing technology was accessible through the Thai generic producer — circumventing the trade secret manufacturing knowledge gap that would otherwise have rendered the license inoperable for immediate domestic production. This pragmatic circumvention through international technology sourcing does not, however, resolve the underlying normative tension: had no accessible third-party manufacturer existed, the trade secret protection over Merck's manufacturing process would have substantially impeded operability of the compulsory license.

Mechanism and Indonesian implication

Brazil's ANVISA prior consent mechanism — requiring ANVISA approval before pharmaceutical patents take effect — provides a more systemic regulatory model. ANVISA's joint patent examination with the National Institute of Industrial Property (INPI) creates a health-sector-specific IP governance architecture that subjects pharmaceutical patent applications to health impact review before grant. This institutional coordination model is directly applicable to Indonesia: a formal BPOM–DJKI joint examination protocol for pharmaceutical and medical device patents, with mandatory assessment of compulsory licensing operability (including whether manufacturing know-how is publicly accessible), would address the patent–trade secret tension at the point of IP grant rather than at the point of compulsory license activation.

Case 3: AstraZeneca AB v. European Commission (EU General Court, 2010; Court of Justice, 2012)

Case facts and decision

AstraZeneca was found by the European Commission to have abused its dominant position through two practices: (1) making misleading representations to patent offices in several EU member states to obtain supplementary protection certificates (SPCs) to which it was not entitled; and (2) selectively deregistering the marketing authorization for Losec capsules (omeprazole) in three EU countries, preventing parallel imports and delaying generic entry. The Court of Justice upheld the Commission's finding that the deregistration constituted abuse of dominant position, even though AstraZeneca had a legal right to withdraw the marketing authorization.

This case illustrates a specific form of Type 1 and Type 3 overlap abuse: the use of regulatory data protection (which operates analogously to a copyright claim over regulatory submissions) combined with strategic patent management to extend effective exclusivity beyond its normative scope. AstraZeneca's deregistration strategy exploited the intersection between regulatory data exclusivity, patent protection, and marketing authorization rights — three legally distinct instruments applied in coordinated fashion to obstruct generic entry.

Mechanism and Indonesian implication

The EU's regulatory response operated through competition law rather than IP law reform: the Commission applied Article 102 TFEU (abuse of dominant position) to constrain the anti-competitive

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use of legitimate IP and regulatory rights. The key doctrinal innovation was the Court's recognition that exercising a legal right (withdrawing a marketing authorization) can constitute an abuse when it is done exclusively to obstruct generic competition. For Indonesia, this case establishes the KPPU (Business Competition Supervisory Commission) as a legitimate — and in some respects more immediately operable — enforcement channel for IP overlap abuse than IP law reform. KPPU's existing mandate under Law No. 5/1999 on Anti-Monopoly and Unfair Business Competition could be interpreted to cover coordinated multi-regime IP deployment that is demonstrably aimed at extending health product exclusivity beyond its normative scope.

Table 3. Comparative regulatory mechanisms addressing IP overlap in the pharmaceutical sector: India, Brazil, and European Union

Jurisdiction	Mechanism	IP Overlap Typology Addressed	Documented Outcome	Indonesia Applicability
India (Patent Act, S.3(d))	Restricts patentability of new forms of known substances without enhanced efficacy; anti-evergreening provision	T2 (Patent–Trade Secret): narrows field available for patent–TS alternation; T4 (Triple): reduces patent component of triple overlap	Novartis (2013): prevented evergreening of imatinib; sustained generic availability; global replication in LMIC advocacy	Patent Act amendment to introduce enhanced efficacy standard for pharmaceutical patents; addresses Type 2 and 4 overlap at grant stage
Brazil (ANVISA joint examination)	ANVISA prior consent for pharmaceutical patents; joint examination with INPI creates health-impact review at patent grant	T2 (Patent–Trade Secret): manufacturing operability assessed prior to grant; T4: health impact assessed across all IP components	Efavirenz CL (2007): effective generic access achieved; ANVISA mechanism identified ~40% of pharmaceutical patent applications as problematic	BPOM–DJKI joint examination protocol; mandatory compulsory licensing operability assessment at patent registration
European Union (Competition law + data exclusivity)	Article 102 TFEU (abuse of dominance) applied to IP exercise; structured data exclusivity with defined generic reliance rights	T1 (Copyright–Trade Secret): structured data exclusivity limits copyright lock-in of safety data; T3: competition law constrains copyright extension beyond patent term	AstraZeneca (2010–2012): abusive deregistration and SPC misuse penalized; deterrence effect on coordinated IP abuse strategies	KPPU mandate extension to pharmaceutical IP overlap; structured BPOM data exclusivity with defined generic reliance rights after expiry

IP = Intellectual Property; CL = Compulsory License; INPI = National Institute of Industrial Property (Brazil); TFEU = Treaty on the Functioning of the European Union; SPC = Supplementary Protection Certificate; LMIC = Lower-Middle-Income Country; BPOM = National Agency of Drug and Food Control; DJKI = Directorate General of Intellectual Property; KPPU = Business Competition Supervisory Commission.

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Proposed Operationalized Harmonized Legal Protection Framework

The five-principle harmonized framework proposed in this study (Table 4) is designed as a semi-operational regulatory instrument — not merely a normative declaration — with defined regulatory actors, assessment criteria, and enforcement pathways for each principle. Figure 1 presents the corresponding regulatory decision tree for application by Indonesian IP and health authorities.

Table 4. Operationalized five-principle harmonized legal protection framework for IP governance in Indonesia's pharmaceutical and medical device sector

Principle	Operational Definition	Triggering Condition	Assessment Criteria	Responsible Actor	Enforcement Pathway
① Object differentiation	Classify each IP claim in a health product registration by regime (copyright/patent/trade secret); prohibit cross-regime claims for same object	Any health product IP registration involving ≥2 regime claims	Does each claimed object fall within the exclusive functional scope of the claimed regime? Is there overlap between claimed objects?	DJKI (at registration); BPOM (at product authorization)	IP registration rejection; BPOM market authorization condition; Commercial Court on dispute
② Functional alignment	Prohibit use of one regime to extend exclusivity beyond the functional scope of another (e.g., copyright over expired patent-equivalent content; trade secret over patent-mandated disclosures)	IP claim that would extend exclusivity beyond regime's normative duration or scope	Does the claim serve the functional purpose of the invoked regime, or does it merely substitute for a right that would not be available under the appropriate regime?	DJKI (substantive examination); KPPU (anti-competitive use)	Refusal of claim; competition law enforcement; BPOM data reliance rights after exclusivity expiry
③ Inter-regime harmonization	Acknowledge legitimate multi-regime coexistence with documented functional boundary mapping; require IP	All complex health product registrations (pharmaceutical products with ≥ patent + one other	Is the functional boundary between each concurrent IP claim clearly delineated? Is manufacturing know-how accessible for	Joint DJKI–BPOM review committee	IP boundary declaration as condition of product registration; CL operability certificate required for patent registration

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	boundary declaration in health product registrations	regime; medical devices with embedded software)	CL operability?		
④ Legal certainty	Establish public IP classification register for health products with regime-specific disclosure; standardize IP expiry notification for generic market entry planning	All registered pharmaceutical and medical device IP	Is the scope, duration, and regime classification of each IP claim publicly accessible to generic manufacturers, competitors, and regulators?	DJKI (public register); BPOM (integration in product database)	Generic manufacturer notification system; Commercial Court reference standard for IP scope disputes
⑤ Public health balance	Require mandatory public health impact assessment (PHIA) for any IP claim or IP combination that may restrict access to essential health products; integrate Doha Declaration flexibilities as default interpretive standard	Any IP claim on WHO Essential Medicines List products; any triple-regime overlap (Type 4); any patent term > 15 years with active trade secret co-protection	Does the aggregate IP protection generate disproportionate exclusivity relative to the innovation incentive? Is the access-to-health obligation (Art. 28H UUD 1945; Art. 4 Law 17/2023) satisfied?	DJKI + Kemenkes + BPOM + KPPU joint public health committee	PHIA publication; CL activation protocol; KPPU competition review; judicial interpretation guidelines operationalizing Doha Declaration

CL = Compulsory License; PHIA = Public Health Impact Assessment; DJKI = Directorate General of Intellectual Property; BPOM = National Agency of Drug and Food Control; KPPU = Business Competition Supervisory Commission; Kemenkes = Ministry of Health; WHO EML = WHO Essential Medicines List.

Figure 1 presents the semi-operational regulatory decision tree corresponding to the five-principle framework. The decision tree provides a step-by-step assessment protocol: from initial IP object classification through overlap typology identification, five-principle testing, public health threshold determination, and resolution (harmonized multi-regime protection permitted; or activation of

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compulsory licensing, regime scope reduction, or KPPU competition review). The decision tree is designed for joint application by DJKI, BPOM, Kemenkes, and KPPU personnel and for adoption as a judicial reference standard by the Commercial Court in pharmaceutical IP disputes.

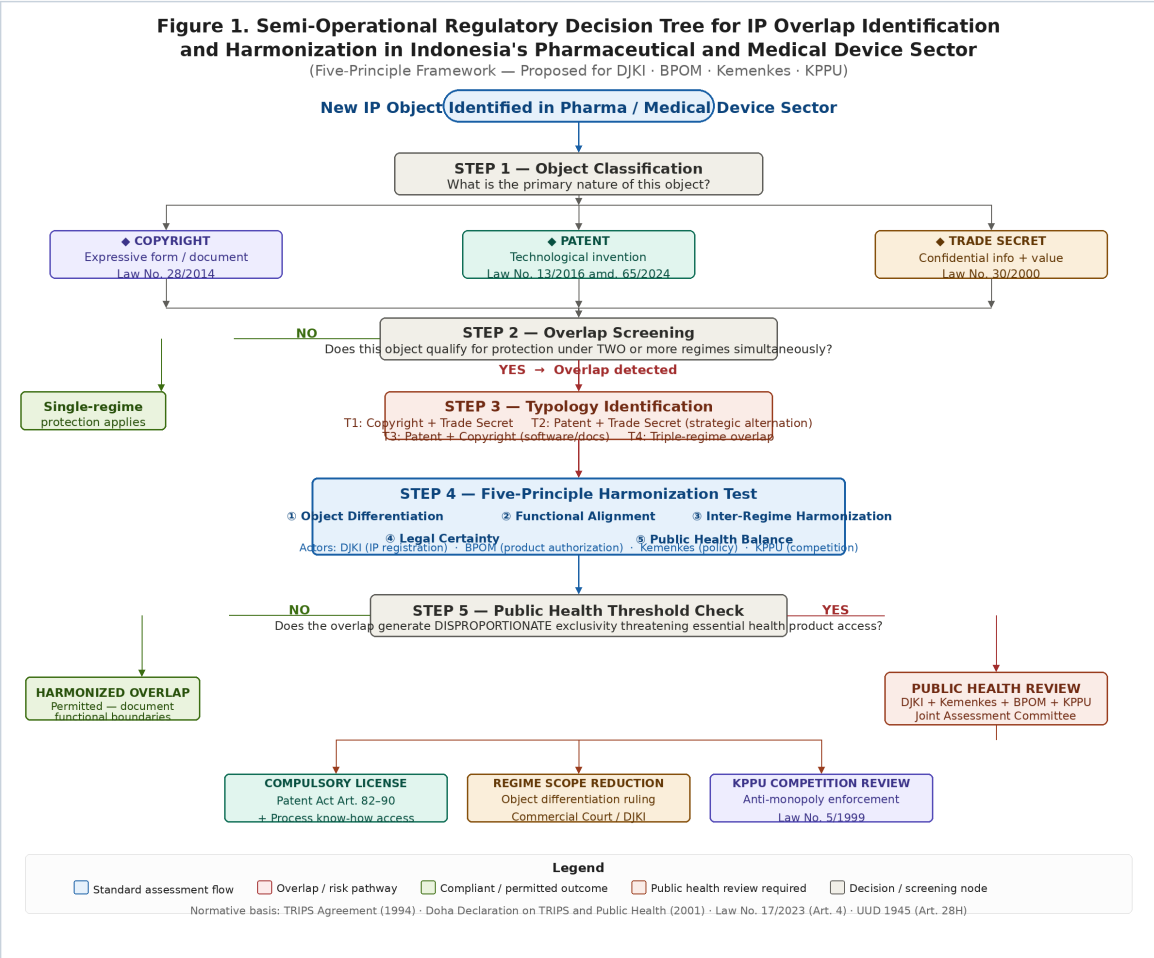

Figure 1. Semi-operational regulatory decision tree for IP overlap identification and harmonization under the proposed five-principle framework. T1–T4 = overlap typology categories; DJKI = Directorate General of Intellectual Property; Kemenkes = Ministry of Health; BPOM = National Agency of Drug and Food Control; KPPU = Business Competition Supervisory Commission; CL = Compulsory License.

DISCUSSION

IP Overlap as a Structural Feature of Pharmaceutical Innovation Systems

The typological analysis demonstrates that inter-regime IP overlap in Indonesia's pharmaceutical and medical device sector is not an exceptional regulatory aberration but a structurally predictable consequence of applying three independently designed IP regimes to objects that are inherently multidimensional.[1,3,5] A pharmaceutical product's compound (patent), its clinical trial documentation (copyright), and its manufacturing process parameters (trade secret) are legally distinct objects governed by distinct regimes — yet they are commercially, technically, and functionally integrated components of a single product system.[5,18] Regulatory frameworks that treat each regime in isolation necessarily generate uncoordinated exclusivity landscapes.[1,12]

The cumulative exclusivity effect of Type 4 (triple-regime) overlap is the most acute manifestation of this structural problem. International health law scholarship has established that excessive IP exclusivity is a primary structural barrier to access to essential medicines in lower-middle-income countries.[1,21,22] Indonesia's specific vulnerability lies in the combination of formally available TRIPS flexibilities (particularly compulsory licensing) with practically inoperable activation pathways — the latter a direct consequence of the patent–trade secret tension documented in Section 3.3.1.[1,4,11,20]

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The Patent–Trade Secret Tension: Indonesia's Critical Compulsory Licensing Gap

The tension analysis in Section 3.3.1 identified what may be Indonesia's most consequential pharmaceutical IP governance gap: the structural nullification of compulsory licensing by trade secret protection of manufacturing know-how. This gap has not been addressed in either the original Patent Act or the 2024 amendment. The Brazilian Efavirenz case (Section 3.4.2) demonstrates that this gap can be pragmatically circumvented through international technology sourcing — but this option is contingent on the availability of an accessible third-party generic manufacturer, which cannot be guaranteed, particularly for innovative medical device technologies.[15,21]

The India Section 3(d) model and Brazil's ANVISA joint examination mechanism both partially address this gap at the patent grant stage by narrowing the patent portfolio available for patent–trade secret alternation.[8,21,22] Indonesia's 2024 Patent Act amendment, while strengthening compulsory licensing procedural provisions, does not directly address the manufacturing know-how gap.[10] A legislative solution would require either: (a) a provision mandating that pharmaceutical and medical device patent registrations include a declaration of whether manufacturing processes are maintained as trade secrets, with compulsory licensing operability as a condition of patent grant; or (b) a judicial doctrine — potentially developed through KPPU guidelines — treating manufacturing process trade secrecy as an anti-competitive barrier when it demonstrably frustrates compulsory licensing operability.[1,4,20]

Copyright–Safety Data Tension: Implications for BPOM Regulatory Capacity

The copyright–trade secret tension analyzed in Section 3.3.2 directly affects BPOM's regulatory capacity for generic product approval. The EU AstraZeneca case (Section 3.4.3) provides a directly applicable regulatory model: the EU's structured data exclusivity framework establishes defined periods during which generic manufacturers cannot rely on originator data, followed by clearly defined generic reliance rights after expiry.[16,17] This framework resolves the copyright–trade secret tension by creating a sui generis regulatory data protection regime that supersedes both copyright and trade secret claims in the regulatory submission context.[2,5]

Indonesia currently lacks an equivalent structured regulatory data protection framework. BPOM's data handling obligations are governed by provisions in the Patent Act that create ambiguity rather than clarity — particularly regarding the duration and scope of data exclusivity and the conditions under which generic manufacturers may rely on previously submitted data.[2,9] Developing a clear regulatory data exclusivity framework — analogous to the EU model, calibrated to TRIPS Article 39.3 obligations and Doha Declaration flexibilities — would resolve the copyright–trade secret tension in the regulatory submission context while protecting legitimate innovation incentives during the exclusivity period.[2,19,21]

The Strategic Role of Competition Law and KPPU in Addressing IP Overlap Abuse

While reform of Indonesia's IP statutes remains necessary, it is insufficient to address the strategic nature of multi-regime IP overlap; as illustrated by the AstraZeneca case, competition law offers a more immediate and flexible enforcement mechanism against coordinated IP-based exclusionary practices. In this context, KPPU holds a critical yet underutilized mandate under Law No. 5/1999 to address anti-competitive conduct, including the strategic combination of patents, trade secrets, copyright, and regulatory exclusivities to delay generic entry. This study positions KPPU as a complementary enforcement channel alongside DJKI and BPOM, enabling intervention even in the absence of immediate IP reform, particularly where lawful rights are exercised to produce exclusionary market effects inconsistent with public health objectives. Operationally, this requires the development of specific KPPU guidelines on pharmaceutical and medical device IP overlap—covering practices such as evergreening, regulatory gaming, and strategic trade secret withholding—thereby establishing a dual-layer regulatory approach combining ex ante IP system design with ex post competition law enforcement.

Operationalization: From Normative Framework to Regulatory Practice

The five-principle framework's value lies in its operationalization (Table 4) rather than in the principles themselves. Three features distinguish this framework from prior normative propositions. First, each principle is assigned specific triggering conditions, assessment criteria, responsible actors, and enforcement pathways — enabling application by regulatory personnel without requiring case-by-case legislative interpretation.[12,13] Second, the five principles are sequenced in the decision tree (Figure 1) as a

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hierarchical assessment protocol that matches decision points to the appropriate regulatory actor, creating a division of labor between DJKI (IP registration), BPOM (health product authorization), Kemenkes (health policy), and KPPU (competition enforcement).[6,13] Third, the public health balance principle (Principle 5) operationalizes the Doha Declaration and Indonesia's constitutional health access obligation as a mandatory assessment criterion rather than an aspirational policy goal.[2,6,21]

The BPOM–DJKI joint examination protocol, modeled on Brazil's ANVISA–INPI mechanism but adapted to Indonesia's institutional architecture, is the most structurally significant institutional recommendation.[15,22] Joint examination at the patent registration stage — rather than dispute resolution at the enforcement stage — shifts the regulatory burden from reactive litigation to proactive IP system design.[14,16] This shift is particularly important for Indonesia given the limited capacity and caseload constraints of the Commercial Court in pharmaceutical IP disputes.[12,13]

Limitations and Future Research

Four limitations should be acknowledged. First, as a normative juridical study, this analysis does not quantify the empirical magnitude of access barriers attributable to IP overlap in Indonesia, which would require pharmaceutical market data and health economics modeling. Second, the three case studies were selected to illustrate specific overlap dimensions and do not constitute a systematic review of pharmaceutical IP case law; a comprehensive comparative analysis would require examination of additional jurisdictions. Third, the proposed decision tree requires pilot testing with regulatory personnel to assess practical feasibility and identify implementation barriers. Fourth, this study does not address the interaction between IP overlap and Indonesia's National Formulary (Formularium Nasional) procurement system, which represents an important extension for establishing the access-to-medicines implications of IP governance reform.

CONCLUSION

This study has demonstrated that inter-regime IP overlap in Indonesia's pharmaceutical and medical device sector constitutes a structurally significant and systematically underregulated challenge with direct consequences for public health access and TRIPS flexibility operability. Four overlap typologies were identified, with Type 2 (patent–trade secret strategic alternation) and Type 4 (triple-regime overlap) posing the highest public health risk through their respective structural nullification of compulsory licensing and maximum exclusivity accumulation effects.

Tension analysis identified two critical irreconcilable normative conflicts: the patent–trade secret compulsory licensing gap, which renders Indonesia's formally available TRIPS compulsory licensing flexibility practically inoperable for products whose manufacturing processes are maintained as trade secrets; and the copyright–trade secret regulatory data access conflict, which impedes BPOM's regulatory capacity for generic product approval when safety documentation is protected under both regimes simultaneously.

Case-based comparative analysis of Novartis v. India (2013), Brazil's Efavirenz compulsory license (2007), and the EU AstraZeneca case (2010–2012) demonstrated that regulatory responses to IP overlap are legally feasible and practically effective within the TRIPS framework, and identified three mechanisms with direct applicability for Indonesia: a Section 3(d)-equivalent anti-evergreening provision in the Patent Act; a BPOM–DJKI joint pharmaceutical patent examination protocol modeled on Brazil's ANVISA–INPI mechanism; and KPPU competition law enforcement as a complementary channel for addressing coordinated multi-regime IP abuse strategies. Importantly, KPPU competition law enforcement should be positioned not as a secondary option but as a critical complementary mechanism to IP law reform, providing an immediately operable pathway to address anti-competitive multi-regime IP practices that delay generic entry and restrict access to medicines.

The proposed operationalized five-principle harmonized framework — comprising object differentiation, functional alignment, inter-regime harmonization, legal certainty, and public health balance — and the associated regulatory decision tree provide a semi-operational instrument for implementation by Indonesian IP and health regulatory authorities. The framework operationalizes Indonesia's Doha Declaration commitments and constitutional public health access obligation (Article 28H,

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UUD 1945; Article 4, Law No. 17/2023) as binding assessment criteria rather than aspirational policy principles.

Future research priorities include: empirical quantification of access barriers attributable to IP overlap in Indonesia's pharmaceutical market; health economics modeling of the access-to-medicines impact of the proposed legislative reforms; stakeholder consultation and pilot testing of the regulatory decision tree with DJKI, BPOM, Kemenkes, and KPPU personnel; and comparative validation of the framework's applicability in analogous LMIC pharmaceutical governance contexts.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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