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Preventing Patent Evergreening through Substantive Examination: A Comparative Study of Indonesia, Japan, and India

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Abstract: This article investigates how substantive patentability standards under the TRIPS Agreement, particularly novelty, inventive step, and industrial applicability, function as regulatory tools for filtering legitimate inventions from strategic attempts to extend market exclusivity. Through a contextual comparative study of Japan, India, and Indonesia, the research demonstrates that the efficacy of substantive examination depends not only on statutory articulation but also on institutional competence, interpretive traditions, and the extent of public oversight. Japan illustrates how a technically rigorous and methodologically consistent examination system, grounded in the problem–solution approach, limits evergreening even without an explicit prohibition on incremental pharmaceutical patents. India offers a contrasting model in which Section 3(d) operates as a substantive barrier to patent claims that fail to demonstrate meaningful therapeutic enhancement, supported by active judicial review and robust civil-society engagement. Indonesia presents a legal framework that is formally compliant with TRIPS yet substantively vulnerable due to limited examiner capacity, fragmented examination guidelines, incomplete prior-art resources, and the absence of effective opposition mechanisms. The analysis argues that Indonesia would benefit from a hybrid strategy that integrates Japan's technical precision with India's normative safeguards, accompanied by reforms in institutional governance, examiner training, data infrastructure, and transparent participatory mechanisms. Such an integrated approach would strengthen patent quality, mitigate the risk of evergreening, and better align the national patent regime with broader public-health objectives.

Keywords: Patent law; Section 3(d), Japan Patent Office; Indonesia patent system; comparative intellectual property

I. Introduction

The debate on patent evergreening occupies a crucial position in the modern intellectual property law perspective. Amidst the acceleration of innovation in pharmaceuticals, biotechnology, and digital technology, the practice of extending patent monopolies through additional claims that are minor and insignificant has raised fundamental questions about the purpose of the patent system itself (1). Patents, in their classical conception, are designed as a mechanism that provides compensation in the form of exclusivity to inventors so that new innovations can continue to develop and progress. However, when exclusivity is maintained not because of new breakthroughs, but through gradual strategies with minimal technological value, the patent system faces a normative dualism that is rationally contradictory (2).

This is where normative tension arises. Monopoly rights, which should encourage innovation, can instead become barriers to competition and access to medicines, especially in developing countries (3). Kapczynski describes this condition as a "shift in the function of patents," whereby a legal instrument that should encourage the creation of new knowledge becomes a tool for maintaining market dominance without meaningful innovative justification (4). Correa emphasizes that an environment that is too permissive of patents that develop gradually without significant invention will cause drug prices to be disproportionate to their technological contribution (5). This results in delays in the availability of more affordable generic drugs. Discourse on innovation in economics has examined the long-term risks of this practice of , namely 1) market imbalances that disrupt healthy and efficient competition mechanisms, especially in the field of patents; 2) the weakening of open innovation; and 3) the cessation of further research due to knowledge being held back within the framework of prolonged monopolies.

The above issues are highly relevant to Indonesia. The development of the national pharmaceutical industry, the growth in patent applications, and the demand to strengthen domestic research capacity place Indonesia in a position that requires a substantive examination system that not only meets formal standards but also is sensitive to the risks of evergreening. Law No. 13 of 2016 has indeed adopted the standards of novelty, inventive step, and industrial application as universally applicable. However, the existence of these substantive norms does not guarantee a rigorous substantive examination. The limited number and specialization of examiners, the lack of an adequate prior art database, and the absence of technical instruments to measure the significance of technological benefits make the examination process prone to incrementalism bias (6).

A number of studies have indicated that Indonesia is still in the stage of institutional capacity building, so that examiners often work in an institutional environment with systemic structural constraints that are not easily resolved. Mirandah notes that some patents accepted in Indonesia are likely to face rejection in jurisdictions with strict examination traditions such as Japan or Europe, especially in the field of pharmaceuticals (7). WIPO, through its regional report, emphasizes that developing countries often face technical obstacles in objectively assessing the inventive step due to limited access to scientific literature and technology databases. Such conditions allow for incremental improvements that should be rejected in an ideal system, but still pass as valid patents (8).

To see how substantive examination can function as an effective instrument for controlling evergreening, attention can be focused on two Asian countries that offer different approaches, but are still relevant to the Indonesian context. Japan has built an examination system based on the technical expertise of examiners, the use of comprehensive prior art databases that are , and inventive step evaluation guidelines that are continuously updated through administrative practices and developments in jurisprudence. In such a construction, the level of technical precision in examination becomes a natural filtering mechanism for incremental claims. Thus, even though there is no explicit prohibition in the law, the system effectively limits the granting of patents for inventions that do not demonstrate a significant increase in technological value (9).

In contrast to the above, India has chosen a more stringent normative approach. Through Section 3(d) of the Patents Act, India has established specific criteria for incremental pharmaceutical patents and requires evidence of significant therapeutic efficacy improvements. Novelty in formulation or structural variation is not considered sufficient if it is not accompanied by empirical evidence showing a real improvement in the ability of a treatment and the extent to which these changes result in clinical benefits that contribute to higher therapeutic value for patients (10). Thus, this standard places pharmaceutical innovation on the principle that patent monopolies are only warranted when the invention truly improves the quality of treatment, rather than merely extending exclusivity through modifications that have no impact on public health benefits. The Indian Supreme Court's ruling in the Novartis case is a milestone that confirms that formal novelty is not enough; patents must reflect real health benefits for the public. India's approach shows that substantive norms can serve as a barrier to corporate legal creativity in extending monopolies without meaningful innovation (11).

This study places Indonesia in a comparative regulatory framework with the aim of examining how substantive examination systems are designed, implemented, and limited by norms that lead to the prevention of evergreening. The analysis does not stop at a formal comparison between regulations, but also considers the institutional dynamics that affect the quality of examinations, including technical capacity, assessment

instruments, and administrative practices that are then manifested in examiners' decisions. With this approach, the study aims to reveal gaps in the Indonesian examination system that could potentially be exploited as loopholes for incremental patents ( ), while formulating recommendations for evidence-based regulatory reform that links the normative framework with institutional capacity building.

The contribution of this research lies in two interrelated areas. The first area relates to efforts to clarify the relationship between substantive examination and the prevention of evergreening practices. Several studies in Indonesia highlight that the patent examination process is often understood only as an administrative stage to assess the technical feasibility of an application (9) (6). This study shows that the role of examiners is much more important, because the quality of the assessment conducted from the outset will determine whether a patent is truly eligible to be granted or is merely a strategy to extend technological monopoly without providing meaningful benefits to society. Thus, substantive examination cannot be viewed solely as a technical procedure, but also as a method that has consequences for access to medicines, knowledge transfer, and market balance.

The second area lies in the perspective used to formulate recommendations. This study places the experiences of Asian countries as a relevant reference source for Indonesia. So far, global discussions on patents have been more influenced by examples from the United States or Europe, so that institutional models and the needs of developing countries are often neglected. By learning from the technical acumen in Japan's examination mechanism and the strictness of India's norms in limiting incremental patents, this study builds a legal reform framework that seeks to balance the drive for innovation with the protection of public interests. The main objective is to ensure that the patent system not only provides incentives but also ensures that the benefits of the technology created remain accessible and felt by the wider community.

In order for Indonesia to be able to promote a sustainable innovation ecosystem without sacrificing public access to technology and medicines, strengthening the quality of substantive patent examination is a crucial effort. This study outlines how to implement these efforts in a systematic, evidence-based manner that is in line with the development of international patent law , which increasingly demands accountability and sensitivity to social issues.

II. Theoretical Framework

III.

1. Basic Theory of the Patent System

In the conception of intellectual property law, patents are seen as instruments born from a normative meeting point between public and private interests. Patents are not interpreted as absolute rights that naturally attach to inventors, but rather as exclusive rights that can only be obtained through the fulfillment of certain substantive and administrative obligations, especially the obligation to contribute useful knowledge to society. Through the granting of patents, the state promises a monopoly for a certain period of time as a consideration for the inventor's invention. The invention is a technological contribution that meets substantive standards and is therefore worthy of protection (12).

There are three classical theories that explain why the state is willing to grant such a monopoly, namely:(13)

a. Incentive to Innovate Theory

This theory stems from the assumption that innovation requires significant costs and carries high risks. Without protection and monopoly, imitators can easily enjoy the fruits of innovation without bearing the costs of research. Thus, patents serve to create economic incentives that make research and development activities reasonable and attractive. However, this theory only works if patents are selectively granted to inventions that are truly novel and significant. When patents are granted for something that is less essential or a cosmetic modification, the logic of incentives then collapses. Patents change from being a driver of innovation to a barrier to competition.

b. Disclosure Theory

This theory emphasizes the function of publication. The role of disclosure emphasizes the inventor's obligation to disclose complete technical information. Patents function as a source of public knowledge that continuously enriches the technological literature because each applicant is required to provide explanations that can be

replicated by experts in the relevant field. After the protection period ends, the technology automatically becomes part of the public domain. The balance is lost if patents are granted for modifications that do not provide new knowledge, so the public suffers a loss because they do not receive benefits equivalent to the monopoly rights granted to inventors.

c. Prospect Theory

Kitch's theory views patents as instruments for managing the prospects of future technological development. Exclusive rights are considered to prevent minor competing claims that actually hinder further development coordination (1). This theory is relevant for upstream technology, but has the potential to cause excessive market dominance when applied to sectors such as generic drugs or minor modifications that do not provide real benefits to users or patients.

All three theories ultimately emphasize that the social function of patents can only work if the substantive examination system is able to accurately distinguish between inventions that deserve protection and those that do not. If the examination process becomes lax, patents lose their social legitimacy and fail to fulfill their intended purpose.

IV. The Concept of Patent Evergreening

Evergreening is understood as a strategy to extend patent monopolies after the protection period ends by filing derivative patents for modifications that do not meet the criteria for inventiveness (14). In the pharmaceutical industry, this practice is commonly seen in the development of new formulations (salts, polymorphs, isomers, prodrugs) without clinical improvement; changes in dosage or method of administration; the addition of therapeutic indications; or the use of drug delivery devices that do not contain inventive steps (15).

Although these changes appear to introduce novelty, they often do not result in therapeutic benefits or technological advances commensurate with the value of the monopoly sought.

The study of evergreening cannot be simplified into a matter of ethics or corporate behavior, because this phenomenon is formed through the interaction between business strategy and weaknesses in the patent system. The low level of certainty in the inventive step standard is one of the main causes. When the measure of uncertainty is not rigidly formulated or strictly applied, almost any minor variation can be considered an invention. The resulting impact is that the system fails to filter out technology claims that do not make a meaningful contribution (16).

This weakness is exacerbated by the absence of adequate opposition mechanisms or public participation in the patent granting process. A system that does not provide space for third parties to question or challenge the quality of claims results in low-quality patents being issued. As a result, the inventor's obligation to provide a reasonable technological contribution to society is not balanced with the exclusive rights obtained.

Evergreening is a structural issue in patent law. This phenomenon arises not only from companies' efforts to extend commercial protection, but also from the ineffectiveness of substantive standards and administrative procedures in clearly distinguishing between innovations that deserve protection and modifications that do not provide technological added value or relevant health benefits to the wider community. The system's failure to maintain this balance means that patents no longer serve as a social contract that exchanges monopoly for useful knowledge contributions, but merely extend control over the market without a strong basis of legitimacy.

V. Substantive Examination as a Preventive Mechanism

Substantive examination is the most decisive stage in the patent granting process. This stage is not merely an administrative procedure, but a regulatory mechanism that determines who has the right to control a technology for a certain period of time (17). Granting exclusive rights through patents is essentially a political decision on how the market should be regulated and to whom control over technology should be given. When a country decides to grant a monopoly to an invention, that decision not only affects the patent holder, but also determines the direction of competition, the cost of entry for other businesses, and the extent to which the public can access

the technology. Therefore, the quality of substantive examination directly shapes the balance between industrial interests and public needs (18).

Based on this explanation, it can be seen that patents function not only as an instrument of rights protection, but also as a form of social exchange. The state does not merely grant a monopoly to inventors in return for their technological discoveries. Inventors themselves make a tangible contribution to society in the form of knowledge that can be learned, replicated, and further developed from their inventions. Monopolies are only valid when the claims submitted strictly meet substantive requirements. This means that only inventions that offer new knowledge, not merely modifications in appearance or cosmetic improvements, are eligible for exclusive protection (19). In this way, patent law ensures that private rights are not granted gratuitously, but rather as compensation for benefits that actually return to the public.

As a manifestation of this principle, substantive examination performs three normative functions (20):

First, the filtering or gatekeeping function. Examiners must ensure that only inventions that meet the standards of novelty, inventive step, and industrial applicability are eligible for protection. This obligation affirms that exclusive rights are not automatically granted to every discovery, but only to contributions that tangibly and significantly expand the technological knowledge base. Examiners act as guardians of the integrity of the system, ensuring that patent monopolies are granted only when justified by demonstrable technological added value.

Second, the function of preventing abuse. Normatively, the state has an obligation to prevent the use of patent instruments for purposes that are contrary to the spirit of innovation incentives. Efforts to extend monopolies through additional claims that have no relevant technical contribution, such as in the practice of evergreening, must be rejected through the examiner's authority to issue objections or office actions. This function emphasizes that the patent system is not a space for baseless monopolies, but rather an incentive mechanism that must be subject to the limits of public interest.

Third, the corrective function. An accountable patent system does not rely solely on the accuracy of initial examinations. The state must also provide means of correction after a patent is granted, through mechanisms such as opposition, post-grant review, or invalidation. These mechanisms emphasize that the quality of patents is not only the responsibility of the examining authority, but also involves the interests of the wider community, which has the right to reject unwarranted monopolies. Thus, the corrective function is a manifestation of the principle of public accountability in the granting of exclusive rights.

VI. Comparative Legal Theory

Experts such as Konrad Zweigert and Kurt Siehr emphasize that modern legal analysis methods are not only about comparing texts, but also about examining the "spirit and style" of different legal systems, including the socio-economic and cultural contexts in which the law operates (21). To analyze cross-border patent examination systems, it is not enough to simply compare the formal texts of legislation. The contextual-comparative approach is particularly relevant, as it emphasizes that the effectiveness of patent enforcement is greatly influenced by the historical, political, and economic context of each country (22).

Japan was chosen as the first case study because it is an advanced industrial country with patent examiners who have deep technical expertise, supported by significant resources for prior art searches and strict and continuously updated assessment guidelines. The highly technocratic and professional bureaucratic culture in Japan's Patent Office (JPO) makes its patent system very precise, where substantive examinations are conducted with a high degree of accuracy. These conditions show that powerful institutions greatly influence how patent standards are translated into practice, and that the same legal framework (e.g., the requirements of novelty and inventive step) can be operated very strictly when institutions support it.

India was chosen as an example of a developing country that normatively adopts highly progressive patent rules to mitigate the risk of evergreening patents, particularly through Section 3(d) of the Indian Patent Act. This provision provides a clear benchmark, namely that incremental pharmaceutical inventions can only be patented if they demonstrate a significant improvement in therapeutic efficacy. India's choice reflects how the socio-political

context and public health needs, particularly regarding access to affordable medicines, encourage the formation of substantive norms that impose more restrictions.

Indonesia functions as a transitional system. As a country moving towards harmonization with international norms, Indonesia still faces challenges in terms of the technical and procedural capacity of its patent authorities. Although the legal framework, particularly regarding patents, has adopted relatively modern substantive elements, its implementation is still hampered by limited examiner capacity, a lack of comprehensive databases, and low public participation. This situation reflects that the adoption of formal norms does not always guarantee regulatory effectiveness. Local institutions and practices largely determine the extent to which these norms can become effective oversight tools (23).

VII. The Doctrine of Public Interest in the Patent System

The public interest doctrine stems from the idea that every legal policy must be directed at protecting the interests of the wider community by balancing the benefits and burdens it creates. The purpose of regulation is not solely to protect individual rights, but also to ensure that its application does not create social harm (24). This principle is in line with Article 8 of the Trade-Related Aspects of Intellectual Property Rights (TRIPs), which affirms that member states may take necessary measures to protect public health, nutrition, and the public interest in sectors that are important for socioeconomic and technological development, as long as they remain consistent with TRIPs provisions (25).

The doctrine of public interest plays a crucial role in the formulation of intellectual property policy. This concept requires a balance between the exclusive rights granted to intellectual property owners and the public's need for access to knowledge, technology, and products that are essential to public life. In the field of intellectual property, the application of this theory is reflected in the existence of restrictions on exclusive rights, which are intended to prevent excessive abuse of rights. These restrictions aim to ensure that intellectual property protection is not used as a tool of monopoly that hinders the dissemination of science, technology, and health services, which are fundamental needs of society (26).

However, restrictions on exclusive rights must still be designed within a clear, proportional, and applicable legal framework. This is important so that policies that protect the public interest do not eliminate the incentives needed by creators or inventors to innovate. Thus, the public interest doctrine plays a role in ensuring that the intellectual property system can support two things at once, namely the appreciation of individual creativity and the fulfillment of public interests in a fair manner.

The public interest doctrine stems from the idea that the ultimate goal of the patent system is not merely to protect the exclusive rights of inventors, but to ensure that such protection is in line with the interests of the wider community. Exclusive rights are a means; the public interest is the end. In the field of pharmaceuticals, this principle is particularly important because patent decisions directly affect drug prices, patient access, and a country's capacity to fulfill the right to health (3).

VIII. Research Method

This study uses a doctrinal legal approach that views law as a set of norms formulated in written laws (27). This approach is used to examine the provisions of substantive patent examination as regulated in the legal systems of Indonesia, Japan, and India. Doctrinal legal research aims to discover normative truths through an examination of regulations, doctrines, administrative guidelines, and the legal principles underlying the provisions for granting patent rights. Thus, this study focuses on how substantive examination norms are formed, implemented, and limited by the legal systems of each country (28).

The research specification is descriptive in nature, as this study is intended to provide an empirical-normative description of the application of substantive patent examination, both as a screening instrument for invention claims and as a mechanism for limiting monopolies. This study not only explains the provisions of Law No. 13 of 2016 concerning Patents and its amendments, but also compares them with Japan Patent Act No. 121 of 1959 and Indian Patents Act 1970 along with their administrative instruments. Through this descriptive

specification, the study outlines the legal structure of substantive examination, the technical standards applied, and its normative implications for controlling evergreening practices.

All data sources used are derived from library research. The main data consists of secondary legal materials comprising three types of materials. First, primary legal materials that have binding authority, consisting of the 1945 Constitution of the Republic of Indonesia, laws and ministerial regulations related to patents, Japan Patent Act No. 121 of 1959, Indian Patents Act 1970, and international TRIPs provisions. Second, secondary legal materials in the form of academic literature, patent examination guidelines such as the JPO Examination Handbook and IP India Manual, scientific journals, court decisions, and reports from international institutions such as WIPO, WHO, and UNDP that provide empirical analysis of the impact of patent policy on access to technology and public health. Third, tertiary legal materials in the form of supporting references such as general dictionaries, Black's Law Dictionary, corporate articles, and online databases used to clarify technical terms and regulatory contexts.

Through a combination of doctrinal and comparative analysis approaches, this study assesses the adequacy of substantive examination norms in preventing the granting of patents that do not meet the requirements of inventiveness. This approach is combined with contextual interpretation to understand that the effectiveness of regulations depends not only on the text of the law, but also on the institutional capacity, bureaucratic culture, and public policy orientation of each country. As stated by Zweigert and Kötz, legal comparisons cannot be separated from the social and institutional structures that shape their application, so that seemingly similar rules can produce different consequences when applied in different contexts.

IX. Research Results and Discussion

The TRIPS Agreement sets three substantive requirements as minimum requirements for patents, namely novelty, inventive step, and industrial application. These provisions are not only formal standards, but also function as normative mechanisms that limit the granting of exclusive rights to claims that truly contribute to the development of science and technology created with significant utility (29).

Article 27(1) of TRIPS emphasizes that not every technical claim is eligible for a monopoly; claims must exceed the minimum threshold of technological creativity. The disclosure requirement in Article 29(1) requires sufficient description so that experts in the field can carry out the invention, thereby enabling patents to also function as instruments for disseminating knowledge. Article 30 allows countries to establish limited exceptions to exclusive rights so that corrective mechanisms such as oppositions or revocations can be justified in order to protect the interests of third parties and the public interest.

The practice of substantive examination tests the extent to which these norms are implemented in an administrative decision. Japan uses a relatively consistent problem–solution approach to assess inventive step, requiring evidence of an unexpected technical effect or a real technical problem solution to recognize an inventive step. This approach makes cosmetic modification claims, such as changes in salt form or polymorph, difficult to pass unless the applicant can demonstrate a significant technical effect (30).

On the other hand, India translates the strictness of substantive norms into explicit restrictions through Section 3(d) of the Patents Act, which denies patents for new forms of substances that do not demonstrate a significant improvement in therapeutic efficacy (31). The Indian Supreme Court's decision in the Novartis case confirmed that improvements in physical properties such as bioavailability without evidence of therapeutic improvement do not qualify for a patent (32).

Indonesia has a normative framework that includes elements of TRIPS, but the facts on the ground show that patent examination practices indicate that the norms in TRIPS have not been consistently applied. In practice, the determination of inventive step in Indonesia often depends on the subjective assessment of the examiner without detailed operational guidelines. This creates opportunities for the granting of patents for claims that, in the assessment of other jurisdictions, do not meet the criteria for patentable inventions.

Referring to the above findings, it can also be concluded that the main problem does not only lie in the existing regulations. Furthermore, these regulations must be properly applied in the examination process. The quality of implementation depends on the availability of guidelines that help examiners interpret and apply the

norms consistently. Without clear guidelines, substantive provisions become nothing more than idealistic legal formulations that are incapable of preventing the granting of patents that are not actually eligible. This line of thinking is in line with literature that shows that patent quality is determined more by examination practices than by the wording of norms in legislation.

A patent office's competence to apply substantive requirements consistently depends heavily on its institutional capacity. The technical capabilities of examiners, the ratio of examiners to the number of applications, the quality of and access to prior art sources, and the quality assurance mechanisms in the preparation of decision reasons shape the selective ability of the office. The Japan Patent Office (JPO) has emerged as a rising star and best practice in all aspects in this context. Examiners in Japan generally have a background in science or engineering, receive intensive training, and are supported by extensive access to patent databases and international technical literature . The JPO's highly structured and technically evidence-based decision-making process creates a culture where rejection is a scientific consequence, not something to be avoided. This process makes patent standards in Japan higher than in jurisdictions where reasoning is not as thoroughly documented (30).

On the other hand, this JPO mechanism does not contain substantive norms explicitly designed to protect public pharmaceutical interests or access to medicines. The Japanese patent system is built with a very strong technocratic orientation where the assessment of patent eligibility focuses almost entirely on the technical aspects of the invention, namely the fulfillment of the requirements of novelty, inventive step, and industrial application, without considering the social implications of granting such a monopoly. In other words, there are no normative principles that specifically limit patents for drugs that only produce marginal therapeutic benefits, even though such claims have the potential to extend monopolies and hinder price competition (33).

The absence of explicit norms has an impact on how examiners and courts interpret substantive evaluations. Technical reasoning becomes the sole benchmark, so that assessments of inventions in the field of pharmacy are made without taking into account their impact on public health policy. As a result, restrictions on evergreening in Japan occur not because of considerations of drug access, but mainly because of strict and carefully documented inventive step standards. If an invention fails to prove an unexpected technical effect or a significant scientific improvement, the claim is rejected (33). However, if such technical evidence can be presented, there is no norm preventing the granting of a patent even if the clinical benefits do not have a significant social impact.

With the above mechanism, Japan has succeeded in maintaining its high patent standards. However, this success is the result of institutional strength and technical logic, not a form of policy aimed at protecting pharmaceutical access. Therefore, the Japanese system cannot be used as a model for public pharmaceutical regulation directly. Its effectiveness in preventing evergreening arises incidentally as a side effect of a culture of strict technical assessment, not from the design of norms for the sake of public health (34). For countries such as Indonesia, which have an urgent need to balance innovation incentives with access to medicines, Japan's technocratic system needs to be complemented with more explicit substantive norms so that social objectives do not depend solely on the adequacy of technical evidence.

India shows a different but still effective configuration in its own domain. Although technical capacity may vary between units, the existence of Section 3(d) provides a clear normative benchmark for incremental pharmaceutical claims. Thus, examiners do not need to conduct costly technical evaluations to reject incremental claims. The Novartis ruling ensures that this approach has judicial legitimacy so that it cannot be challenged by industries seeking to extend patent monopolies (35).

Although Section 3(d) is seen as an effective normative instrument to curb evergreening practices, this provision is not without serious criticism. First, some industry circles argue that the wording of Section 3(d) is too restrictive on innovation, especially in the pharmaceutical sector. The provision stipulates that modifications to existing drug products can only be patented if they are proven to result in significant therapeutic efficacy improvements. With strict standards of proof, many incremental developments that actually have the potential to result in clinical improvements or benefits in the production process are considered ineligible and therefore do not obtain patent protection (36).

Second, the requirement to prove "significant therapeutic efficacy improvement" in practice demands clinical data that is not inexpensive. This burden of proof is relatively easier to meet for multinational companies with the financial capacity to fund large-scale clinical trials, but it becomes an obstacle for domestic inventors or local pharmaceutical companies with limited research capacity. In this context, regulations intended to protect access to medicines have the potential to cause unintended effects, namely narrowing the incentives for innovation for local actors who do not yet have adequate research capabilities (37).

Third, the success of the Indian model cannot be separated from its underlying political-economic configuration. Section 3(d) grew out of a strong history of generic drug industrialization and intense civil society advocacy on public health issues. The combination of national generic industry capacity, the government's economic interest in affordable drug prices, and a tradition of public litigation means that this norm is not only applicable in text, but also supported by an ecosystem ready to defend it. Therefore, applying this model in other countries cannot be done simply by copying the norm. Without local drug production capacity, political support for affordable drug prices, and strong civil society participation, norms such as Section 3(d) risk being ineffective or even counterproductive (37).

A lesson for Indonesia is that criticism of the Indian model is relevant as a reminder that substantive regulations cannot stand alone without institutional capacity support. Indonesia not only lacks operational norms that specifically protect public health interests such as Section 3(d), but also faces institutional limitations that make it difficult to consistently enforce existing norms. This situation creates a double risk: the absence of explicit rules to prevent incremental pharmaceutical patents and weak administrative capacity to reject non-inventive claims.

In this situation, Indonesia faces structural challenges that hinder the selective examination function. A large backlog of applications, a relatively limited number of examiners, limited access to international databases, and a high need for technical training create a trade-off between the depth of analysis and the speed of file completion. Under these conditions, pragmatic practices tend to relax substantive standards, increasing the likelihood of low-quality patents. Empirical literature shows that the quality of patent decisions is closely correlated with the level of training and resource support provided to examiners. Systems that support the development of examiner competence tend to produce decisions that are more substantively robust and more resistant to challenge, both administratively and judicially (19)(6)(38)(11).

This is where public control mechanisms play a strategic corrective role. The involvement of third parties in the examination process is an important counterbalance to administrative limitations. Opposition mechanisms both before and after patent grant provide space for competitors, civil society organizations, and academics to present prior art or legal arguments that may not have been identified by internal examination. India is an example of a country that has intensively implemented this mechanism, where advocacy by non-governmental organizations and generic manufacturers has played an important role in preventing the granting of patents that could potentially lead to evergreening practices. Transparency practices such as the publication of file wrappers strengthen external oversight and incentivize patent offices to maintain strong standards of reasoning (37).

Japan also provides strong corrective measures through post-grant mechanisms and a high level of transparency, enabling stakeholders to understand the basis of examiners' arguments and prepare evidence-based challenges (39).

Indonesia is relatively weak in these aspects. The absence of effective opposition and post-grant practices, low public awareness of opportunities to challenge patents, and cost barriers prevent social control from functioning optimally. As a result, errors in the initial examination stage are more difficult to correct and can lead to monopolies that are not supported by substantial inventive innovation.

This comparison confirms that public control is not merely an additional advocacy tool, but a very important part of the patent examination architecture that ensures accountability. Without accessible corrective mechanisms, the system will rely entirely on the internal capacity of the patent office to enforce substantive norms. When resources and capacity are limited, the quality of patent granting will easily deteriorate. The consequences are not simple, as the function of patents as a driver of innovation can turn into an obstacle to competition and access to technology.

Indonesia faces a dilemma. Normatively, the patent legal framework is in line with international principles in the TRIPS agreement. However, operational limitations at the implementation level prevent these norms from working optimally. The reliance on the subjective assessment of examiners, which is not always supported by adequate prior art data, allows incremental patents to pass substantive selection. In the health sector, this issue has a direct impact on drug policy, namely that extended monopolies through patents without new therapeutic benefits have the potential to delay the availability of affordable generic drugs (11). Therefore, reform recommendations need to be directed at two dimensions simultaneously, namely the affirmation of more detailed substantive guidelines to minimize excessive room for interpretation, and the strengthening of institutional capacity so that these guidelines can be applied consistently.

Japan shows that efforts to improve the quality of examinations through strengthening human resources and technical infrastructure can create a system capable of rejecting evergreening practices without the need for specific normative restrictions. The problem-solution approach applied is capable of preventing non-inventive claims from obtaining protection. However, this model requires significant resources and consistent administrative commitment. Therefore, full adoption of the Japanese model requires long-term projects and trained human resources (40).

India offers an approach that emphasizes normative legitimacy. India demonstrates that explicit substantive norms directed toward the public interest can effectively restrain evergreening, particularly in the pharmaceutical sector. Section 3(d) explicitly directs the patent system to protect the public interest, particularly in the field of pharmaceuticals. These clear substantive norms have proven effective in preventing the extension of monopolies that do not provide new therapeutic value. However, India's success is not without risk. Higher effectiveness requirements can be an additional burden for domestic inventors who do not yet have adequate clinical research capacity. Thus, the effectiveness of the normative approach needs to be accompanied by policies that support national research so that local innovation is not disproportionately affected (41).

A comparison of the three jurisdictions indicates that the success of controlling low-quality patents is determined not only by the content of the law, but also by complementary institutional capacity and public correction mechanisms. A healthy patent system requires a balance between clear substantive norms, strong technical examination, and effective public participation. Without these three elements, the purpose of patents to encourage innovation and improve public welfare risks becoming an unproductive instrument of exclusivity.

Evergreening is not merely a technical issue but a phenomenon that arises from the gap between normative texts and institutional capacity. When substantive norms are vague or their implementation is weak, economic actors can exploit this space to extend their monopoly. Conversely, when norms are strengthened and institutions are reinforced, these opportunities narrow. The policy choice is not about dogmatically imitating one model, but rather selecting the combination of instruments that best suits the institutional context and public objectives (13).

For Indonesia, the most feasible strategy is an adaptive hybrid model that combines the strengths of Japan and India. From Japan, it is necessary to strengthen problem–solution reasoning, improve prior art search capabilities, and implement examiner training programs. From India, it is necessary to formulate more operational substantive norms in sensitive areas such as pharmaceuticals, for example, regulations that require evidence of increased therapeutic efficacy for certain claims. These two elements must be combined with improved public control and transparency mechanisms. This model is not intended to dogmatically imitate India or Japan, but to adapt the elements that are most compatible with Indonesia's institutional structure and public health objectives.

The first reform lies in the establishment of substantive norms that explicitly reject pharmaceutical patents without real technical or therapeutic benefits. These provisions should stipulate that claims for new forms, new indications, or dosage variations that do not result in significant clinical improvements cannot obtain patent protection. The purpose of this norm is not to limit innovation, but to ensure that exclusive rights are only granted to inventions that truly contribute to public health.

Furthermore, examination guidelines need to be clarified by including operational criteria that can guide examiners in consistently applying the inventive step test. These criteria include the use of problem–solution reasoning, assessment of substantial technical advancement, and a list of claim categories that are prima facie

considered non-inventive and therefore require additional evidence from the applicant. Harmonization of these guidelines serves as a bridge between norms and administrative practice, so that they do not depend solely on the individual capacity of examiners.

Strengthening norms will not be effective without adequate institutional support. Therefore, investment in a prior art search system integrated with international databases is a structural urgency. This step needs to be accompanied by a program to improve the competence of pharmaceutical examiners in the fields of chemical informatics, pharmaceutics, biostatistics, and clinical data evaluation methodology. In addition, the establishment of a special pharmaceutical patent unit is needed to handle claims that require clinical evidence-based assessment, following the practices of regulatory agencies such as the FDA and EMA.

Outside of state institutions, public control mechanisms need to be expanded through the application of pre-grant opposition limited to the strategic sectors of pharmaceuticals, biotechnology, and public health technology. This mechanism serves to balance the asymmetry of information between patent applicants and regulators by involving the academic community, the generic industry, and civil society organizations as supervisors of the substantive process. These efforts must be complemented by a patent examination transparency portal that allows the public to access applicants' arguments and the reasons for rejection or approval.

Ultimately, patent system reform must be integrated with public health policy. Patent examination in the pharmaceutical field cannot be limited to technical considerations alone, as these decisions have a direct impact on drug prices, the sustainability of health financing, and equitable access to treatment. Thus, patents should not be viewed merely as an economic instrument that provides incentives for innovation, but as an integral part of public health governance.

A hybrid model that combines strict norms, technical accuracy in examination, and effective public control provides a realistic and progressive policy direction . This approach has the potential to produce a patent system that not only complies with international standards but is also more socially equitable and more credible in supporting innovation that truly benefits society.

X. Conclusion

The main problem in Indonesia's patent system is not merely the absence of new substantive norms, but rather the lack of synchronization between the legal text and the institutional capacity to enforce it. Although Indonesia is normatively in line with TRIPS minimum standards, its implementation has not been able to produce consistent substantive selection. Reliance on individual examiners' assessments without the support of strong operational guidelines creates loopholes for the granting of low-quality patents, particularly in the pharmaceutical sector, which is highly sensitive to the public interest.

A comparative analysis shows that Japan and India are both capable of resisting evergreening practices, but through different channels. Japan relies on technocratic strength, where it has high examiner capacity, broad access to prior art, and a systematic problem-solution approach. However, this effectiveness arises incidentally in the context of public health because Japan does not have explicit norms designed to control incremental pharmaceutical patents. This indicates that strong technical standards can indeed be a natural bulwark against weak patents, but only if supported by substantial resources and stable administrative discipline—two things that Indonesia does not yet have.

In contrast, India explicitly embeds normative restrictions through Section 3(d). This norm is effective because it is supported by an ecosystem that enables its implementation, namely a strong generic industry, aggressive public advocacy, and judicial legitimacy. However, an overly strict normative approach also carries risks. This overly strict approach can limit domestic innovation that does not yet have significant clinical research capabilities. India's success is not solely due to Article 3(d), but also to the surrounding political-economic structure.

From this point, it is clear that copying the Japanese model without adequate technical capacity is an illusion, and adopting the Indian model without a strong industrial foundation and political support will result in ineffective norms. Therefore, Indonesia's solution cannot be imitation, but adaptation.

An adaptive hybrid model is the most rational choice. Substantive norms need to be strengthened, especially for incremental pharmaceutical claims, but they cannot stand alone. These norms must be accompanied by (1) operational examination guidelines based on problem–solution reasoning, (2) strengthening of technical capacity and access to prior art, and (3) public control mechanisms such as pre-grant opposition that can correct institutional bias and examiner limitations. These three pillars are only effective if designed as an integrated architecture, not as a list of separate policies.

This approach not only maintains the integrity of the patent system, but also provides space for public health protection without sacrificing innovations that truly have technical and therapeutic value. With this balance, the patent system is no longer an instrument that is vulnerable to being used to extend monopolies, but returns to its original function: encouraging substantial technological advances that benefit society.

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