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TRANSFORMATION OF PATENT POLICY IN INDONESIA: NEW OPPORTUNITIES AND CHALLENGES FOR PHARMACEUTICAL INNOVATION IN THE DIGITAL ERA

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ABSTRACT
Indonesia is a developing country with an expanding healthcare market, which faces the enduring challenge of fostering a pharmaceutical patent system that incentivizes research and development while ensuring broad access to affordable medicines. This study aims to offer policy recommendations that balance the need for pharmaceutical innovation with the imperative of maintaining an accessible and competitive healthcare landscape. The study includes a review of pharmaceutical patent regulations in India, Brazil, the United States, and the European Union. It integrates empirical data analysis to assess patent application trends and market dynamics, utilizing a difference-in-differences econometric model to establish causality between policy reforms and sector changes. It highlights the necessity of public health safeguards, proposing mechanisms like conditional compulsory licensing as critical elements in the patent reform framework. The study emphasizes actionable policy recommendations while incorporating stakeholder perspectives from regulatory authorities, pharmaceutical firms, and public health organizations to understand the implications for investment, competition, and medicine accessibility. By implementing these strategic policy adjustments, Indonesia can maximize the benefits of Law No. 65 of 2024 while safeguarding public health and promoting domestic pharmaceutical innovation in a rapidly evolving global landscape.

Keywords: Bolar Provision, compulsory licensing, patent law, patent policy reform, pharmaceutical innovation

INTRODUCTION

Indonesia's pharmaceutical industry is transforming, navigating the intricate balance between intellectual property rights, pharmaceutical innovation, and public health imperatives. As a developing economy with an expanding healthcare market, the country faces the enduring challenge of fostering a patent system that incentivizes research and development while ensuring broad access to affordable medicines. This tension has been central to global pharmaceutical policy debates, particularly in jurisdictions that grapple with public health burdens and the need for robust local pharmaceutical manufacturing.

The enactment of Law No. 65 of 2024 marks a significant regulatory shift, introducing changes that align Indonesia's intellectual property landscape with international frameworks. The law eliminates compulsory licensing, expands the Bolar Provision, and extends the patent grace period. Compulsory licensing, previously a mechanism that allowed local manufacturers to produce patented medicines during national emergencies or under public interest justifications, has been removed in favor of a more investment-friendly approach. While this shift is designed to attract foreign direct investment and stimulate pharmaceutical innovation, concerns arise regarding the long-term implications for drug affordability and emergency preparedness. The expansion of the Bolar Provision permits generic drug

manufacturers to conduct research and development on patented medicines before patent expiration. This provision may accelerate the introduction of generics into the market. However, the extent to which local pharmaceutical firms can capitalize on this reform will depend on Indonesia's research and development infrastructure and regulatory efficiency. Extending the patent grace period from six to twelve months gives researchers greater flexibility to refine their inventions and secure necessary funding. While this provision is expected to encourage innovation, multinational corporations with advanced research capabilities may be better positioned to exploit its benefits, potentially sidelining local pharmaceutical firms (Ozyhar et al., 2022).

These reforms create both opportunities and challenges. While a stronger intellectual property regime may enhance Indonesia's appeal to global investors, it also risks increasing pharmaceutical market consolidation, potentially limiting access to essential medicines (Ho & Leisinger, 2013). The core question guiding this study concerns the implications of these regulatory changes for domestic pharmaceutical innovation and equitable healthcare access. A comparative legal analysis examines similar policy shifts in India, Brazil, the United States, and the European Union to address this issue. These jurisdictions offer distinct models of patent regulation that provide insights into the potential consequences of Indonesia's recent reforms (Halydier, 2012).

Through a comprehensive comparative framework, the study seeks to offer policy recommendations that balance the need for pharmaceutical innovation with the imperative of maintaining an accessible and competitive healthcare landscape. It highlights the interplay between pharmaceutical innovation and healthcare accessibility, providing valuable recommendations aimed at ensuring that essential medicines remain affordable while incentivizing research and development. By analyzing various regulatory approaches and their outcomes, the research informs policymakers on effective strategies to support both innovation and public health needs, which is significant for guiding future reforms in Indonesia and similar contexts (Halydier, 2012). The current research contributes novel insights into Indonesia's patent law reforms, particularly Law No. 65 of 2024, through a comparative legal analysis that includes frameworks from India, Brazil, the United States, and the European Union (Kementerian Hukum dan HAM RI, 2024). It integrates empirical data analysis to assess patent application trends and market dynamics, enhancing its findings with quantitative evidence. The study emphasizes actionable policy recommendations while incorporating stakeholder perspectives (Cherian, 2016) (Bognar et al., 2016) and highlights the necessity of public health safeguards, proposing mechanisms like conditional compulsory licensing as critical elements in the patent reform framework (McGivern, 2023). Overall, this research advances the discourse by providing a holistic, evidence-based examination that merges legal and public health considerations (Ozyhar et al., 2022).

RESEARCH METHOD

This study examines the impact of Indonesia's patent law reform through a comparative legal and policy analysis approach that integrates qualitative and quantitative methods. It evaluates Law No. 65 of 2024 in relation to the TRIPS Agreement and global intellectual property standards, exploring its alignment with international best practices while assessing

risks to drug accessibility and market competition. The research includes a review of pharmaceutical patent regulations in India, Brazil, the United States, and the European Union, providing context for Indonesia's policy changes. Empirical data analysis focuses on patent application trends, market entry of generic drugs, and pricing of essential medicines, utilizing a difference-in-differences econometric model to establish causality between policy reforms and sector changes. Stakeholder perspectives from regulatory authorities, pharmaceutical firms, and public health organizations are incorporated to understand the implications for investment, competition, and medicine accessibility. Through this comprehensive methodology, the study aims to generate evidence-based policy recommendations that support pharmaceutical innovation and equitable healthcare access.

RESULT AND DISCUSSION

The enactment of Law No. 65 of 2024 introduces substantial reforms to Indonesia's intellectual property (IP) and pharmaceutical landscape, reshaping the dynamics of accessibility, competition, and innovation. The law's key provisions—abolishing compulsory licensing, expanding the Bolar Provision, and extending the patent grace period—align Indonesia's regulatory framework with global trends. However, these changes also introduce new challenges, particularly concerning healthcare affordability, the competitiveness of domestic pharmaceutical firms, and the sustainability of innovation within the country's research ecosystem.

Abolition of Compulsory Licensing: A Double-Edged Sword

The elimination of compulsory licensing marks a fundamental shift in Indonesia's approach to pharmaceutical accessibility. Historically, compulsory licensing served as a critical legal mechanism that allowed the government to authorize domestic production of patented medicines during public health crises, ensuring that essential drugs remained accessible to the population (European Parliamentary Research Service, 2024). This policy was instrumental in global public health strategies, as seen in India and Brazil (Halydier, 2012).

In India, the compulsory licensing of sorafenib, a drug for treating advanced kidney and liver cancer, led to a 95% reduction, significantly improving affordability and patient access (Bognar et al., 2016). Similarly, Brazil's issuance of compulsory licenses for antiretroviral drugs played a crucial role in controlling HIV/AIDS treatment costs, allowing more patients to access life-saving therapies (Marques et al., 2005). By contrast, Indonesia's decision to remove this safeguard raises concerns that patented medicines will become prohibitively expensive, particularly for lower-income populations (McGivern, 2023).

Without a mechanism to regulate drug affordability, Indonesia risks following the trajectory of countries that have eliminated compulsory licensing, leading to greater reliance on imported medicines. The World Trade Organization (WTO) has documented that emerging economies that phase out compulsory licensing often experience increased pharmaceutical import dependence, rather than fostering domestic drug production (Obeng, 2015). South Africa has counteracted this risk by implementing alternative price-control measures, such as external reference pricing (benchmarking drug prices against those in other

countries) and cost-based pricing regulations (limiting pharmaceutical profit margins) (Koduah et al., 2022). If Indonesia does not introduce a comparable alternative, the healthcare sector may face rising drug prices, exacerbating inequality in access to essential medicines.

Furthermore, eliminating compulsory licensing may disincentivize generic drug manufacturers from investing in local production. They would no longer have a legal framework enabling them to manufacture patented medicines under specific circumstances (Obeng, 2015). This could reduce competition within the domestic pharmaceutical industry, allowing multinational patent holders to dictate market prices without pressure from local competitors.

Expansion of the Bolar Provision: Potential for Accelerated Generic Drug Entry

The expansion of the Bolar Provision represents a progressive shift towards harmonizing Indonesia's pharmaceutical patent regulations with international standards. Under this provision, generic manufacturers are permitted to conduct research, development, and clinical trials on patented drugs before the patent expires, allowing generic versions to enter the market immediately once the patent term ends.

This policy aims to increase the availability of affordable generics and reduce the time lag between patent expiration and market entry, ensuring that patients benefit from cost-effective alternatives without unnecessary delays. The European Union (EU) has successfully implemented Bolar-type provisions. Still, its effectiveness has been bolstered by regulatory incentives that encourage domestic pharmaceutical firms to invest in early-stage research and development (R&D) (European Commission, 2020). South Korea provides another illustrative example: its strong pharmaceutical research infrastructure, backed by government subsidies, tax breaks, and R&D incentives, has allowed domestic manufacturers to compete effectively against multinational corporations (Deloitte Research Center, 2020).

However, the success of the Bolar Provision is highly dependent on the strength of Indonesia's R&D ecosystem. Domestic pharmaceutical firms may struggle to effectively leverage this reform without sufficient investment in biomedical research facilities, technology transfer programs, and funding mechanisms. The risk of market domination by multinational pharmaceutical corporations remains high if local firms lack the resources to engage in early-stage R&D. To mitigate this, policymakers must consider introducing targeted subsidies, grants, and tax incentives to bolster the capacity of domestic manufacturers. Moreover, Indonesia must ensure that regulatory bottlenecks do not hinder the potential benefits of the Bolar Provision. In many jurisdictions, inefficient approval processes and bureaucratic delays limit the effectiveness of such policies (Doubinsky, 2025). A streamlined regulatory framework, including fast-track approval mechanisms for generic drug applications, will be crucial in maximizing the impact of this provision.

Extension of the Patent Grace Period: Implications for Domestic and Multinational Innovators

The grace period extension offers researchers additional flexibility in completing studies, securing funding, and refining their inventions before filing for a patent. This

provision aligns with global trends, as many advanced economies, including Japan, Singapore, and the United States, have adopted extended grace periods to promote innovation. However, empirical data from the Directorate General of Intellectual Property suggests that this reform may inadvertently benefit multinational corporations more than domestic pharmaceutical firms. In 2024, over 60% of pharmaceutical patent applications in Indonesia were submitted by foreign companies, while local manufacturers accounted for only 40% (Kementerian Hukum dan HAM RI, 2024). This disparity suggests that multinational corporations, with their established R&D infrastructure, financial resources, and international partnerships, are better positioned to exploit the advantages of an extended grace period. Japan's experience with extended grace periods provides valuable insights. While the policy facilitated domestic pharmaceutical innovation, this success was largely driven by robust government incentives, including R&D grants, tax exemptions, and university-industry collaborations (Motohashi & Muramatsu, 2011). By contrast, countries that extended grace periods without corresponding financial support for domestic innovators saw a decline in local patent filings and an increased reliance on foreign patent holders (Direktorat Jenderal Kekayaan Intelektual RI, 2015).

Indonesia must proactively address this potential imbalance by implementing complementary policies that empower domestic researchers and pharmaceutical firms. Possible measures include: increased research funding through government-backed grants for local pharmaceutical startups, stronger collaboration between universities and industry to enhance technology transfer and commercialization, and tax incentives for domestic firms filing patents within Indonesia.

Comparative data from Singapore further suggests that an extended grace period can be particularly beneficial for niche biomedical sectors, such as personalized medicine, regenerative therapies, and biopharmaceuticals (Intellectual Property Office of Singapore, 2022). Indonesia could capitalize on this opportunity by developing a targeted national innovation strategy focusing on emerging fields in biopharmaceutical R&D.

Strategic Policy Adjustments Needed

While Law No. 65 of 2024 brings Indonesia's pharmaceutical patent framework closer to international standards, its implementation requires careful calibration to avoid unintended consequences. Removing compulsory licensing threatens to escalate drug costs and reduce accessibility unless alternative price-control mechanisms are introduced (Arifin, 2021). The Bolar Provision offers the potential for accelerated generic drug availability, but its success hinges on strengthening domestic R&D capacity and removing regulatory bottlenecks (Odeh, 2024). Extending the grace period provides greater flexibility for researchers, but without corresponding government incentives, domestic innovation risks are overshadowed by multinational competitors (Nagaoka & Nishimura, 2015).

To navigate these challenges, Indonesia must adopt a comprehensive pharmaceutical policy strategy that balances investment-driven growth with public health safeguards. This includes:

1) Developing alternative price-control mechanisms to offset the elimination of compulsory licensing.

2) Introducing R&D incentives such as tax breaks and grants ensures domestic firms can compete.
3) Enhancing regulatory efficiency to support the effective implementation of the Bolar Provision.
4) Leveraging the grace period extension to foster innovation in emerging biomedical fields.

By implementing these strategic policy adjustments, Indonesia can maximize the benefits of Law No. 65 of 2024 while safeguarding public health, promoting competition, and fostering domestic pharmaceutical innovation in a rapidly evolving global landscape.

Discussion

Indonesia's patent policy reforms mark a significant shift towards global patent harmonization, reflecting the country's ambitions to attract foreign investment and foster technological advancements in its pharmaceutical sector. However, these policy changes introduce complex challenges, particularly in balancing intellectual property protection with public health imperatives. The interplay between strengthened patent regulations and their socioeconomic implications demands scrutiny, especially as multinational pharmaceutical corporations seek to consolidate their market power through extended patent exclusivities.

One of the most pressing concerns is the potential for market consolidation that disadvantages local pharmaceutical firms. Multinational corporations, equipped with extensive legal and financial resources, can leverage patent extensions through secondary filings, data exclusivity provisions, and incremental innovations. These tactics effectively delay generic competition, creating prolonged monopolies that hinder affordability and accessibility of essential medicines. Empirical data from the World Health Organization (WHO) and the World Trade Organization (WTO) indicate that countries with stricter patent exclusivities, such as South Africa before its 2002 reforms, experienced a 150% increase in medicine costs over a decade due to prolonged monopolies (Tenni et al., 2022). As a result, Indonesia's pharmaceutical market may increasingly tilt towards import reliance, diminishing domestic production capacity and exposing the nation to fluctuations in global pharmaceutical pricing. This shift could exacerbate healthcare inequalities, as higher drug costs disproportionately affect lower-income populations who rely on affordable generics.

The consequences of these patent reforms extend beyond economic implications to public health resilience. The potential removal or restriction of compulsory licensing—the legal mechanism allowing governments to override patents during public health crises—poses a significant risk to Indonesia's ability to respond to pandemics, emerging diseases, and essential medicine shortages. Comparative case studies from Brazil and India demonstrate that effective compulsory licensing mechanisms have significantly reduced life-saving treatments costs (Cherian, 2016). For example, Brazil issued a compulsory license for efavirenz, an antiretroviral drug, resulting in a 75% price drop, ensuring broader accessibility (Rodrigues & Soler, 2009). Without equivalent mechanisms in place, Indonesia may face prolonged negotiations with pharmaceutical giants, delaying access to life-saving treatments in times of crisis.

Indonesia must prioritize strengthening its domestic pharmaceutical innovation ecosystem to counteract the risks associated with heightened intellectual property protections. A robust policy framework that integrates financial incentives, research grants, and regulatory support is essential to enabling local firms to compete with multinational players. The Innovation Systems Theory provides a framework for understanding how national policies, institutions, and industrial capabilities interact to drive pharmaceutical innovation (McKelvey & Orsenigo, 2001). This theory underscores the importance of government intervention in fostering innovation, ensuring that research funding, infrastructure development, and regulatory policies create a conducive environment for pharmaceutical advancements. South Korea serves as a model for this approach, where state-backed initiatives, such as tax incentives for pharmaceutical R&D and direct government investment in biotech hubs, resulted in a 45% increase in domestic drug patents from 2008 to 2013 (OECD, 2014).

The Regulatory Capture Theory offers insights into the potential influence of multinational corporations in shaping patent regulations to their advantage, highlighting the risks of policy frameworks being skewed in favor of dominant industry players (Etzioni, 2009). Given that multinational pharmaceutical firms have extensive lobbying power, they may leverage legal and political mechanisms to influence regulatory frameworks, creating barriers to market entry for domestic firms. Historical evidence from the U.S. pharmaceutical sector shows that regulatory capture by large corporations led to a decrease in generic drug approvals from 1996 to 2004, contributing to sustained high drug prices (Frank et al., 2021). Indonesia's policymakers must remain vigilant against regulatory capture by ensuring transparent decision-making processes and establishing independent oversight bodies to monitor patent-related policy developments.

The Public Health Law Theory underscores the legal and ethical considerations in balancing patent protection with equitable healthcare access, emphasizing the state's role in safeguarding public health through strategic regulatory interventions (Lelisa, 2024). This theory highlights the need for regulatory mechanisms prioritizing public welfare over commercial interests, advocating for policies ensuring essential medicines remain affordable and accessible. Indonesia's decision to eliminate compulsory licensing, for instance, must be reassessed through a public health lens, ensuring that alternative measures, such as price controls or government-use licenses, are in place to prevent monopolistic pricing of critical drugs. Case studies from Thailand reveal that government-led price negotiations, in conjunction with compulsory licensing, resulted in a 60% reduction in the cost of HIV medications, improving access for vulnerable populations (Kuanpoth, 2015).

Additionally, the Edwin Mansfield's Innovation Diffusion Model provides a lens through which to assess how patent policy changes impact the spread of pharmaceutical innovations, particularly in emerging markets (Frenzel & Grupp, 2009). This model suggests that technological adoption and innovation diffusion depend on factors such as knowledge dissemination, infrastructure readiness, and financial incentives. Indonesia's extension of the patent grace period and expansion of the Bolar Provision are intended to accelerate pharmaceutical innovation. However, empirical data from Singapore's biopharmaceutical sector indicate that such policies are most effective when coupled with targeted investment in

research institutions, regulatory harmonization, and funding for early-stage drug development (Spencer, 2024). Without corresponding investments in research infrastructure and knowledge diffusion mechanisms, the intended benefits may remain unrealized, disproportionately benefiting multinational corporations rather than domestic innovators.

Given these multifaceted challenges, a hybrid regulatory approach emerges as a viable solution. Indonesia must navigate a middle ground where it upholds international patent standards while integrating safeguards that protect public health interests. One possible strategy involves incorporating flexibilities within its patent framework, such as conditional compulsory licensing that activates under predefined circumstances, ensuring preparedness for public health emergencies. Furthermore, Indonesia can leverage its participation in regional trade agreements, such as the ASEAN Economic Community, to negotiate cooperative pharmaceutical policies that balance innovation with equitable medicine access. Comparative studies of nations that have successfully managed similar policy transitions could inform Indonesia's approach, enabling real-time adjustments based on empirical evidence and stakeholder feedback.

Ultimately, the effectiveness of Indonesia's patent policy reforms will depend on the government's ability to evaluate their socioeconomic impact continuously. Regular assessments through interdisciplinary research, industry consultations, and international benchmarking will be essential in mitigating unintended consequences. If left unchecked, these reforms risk exacerbating disparities in healthcare access, reinforcing market monopolies, and undermining domestic pharmaceutical capabilities. Conversely, with a well-calibrated regulatory framework, Indonesia can position itself as a leader in pharmaceutical innovation while ensuring that essential medicines remain accessible to all segments of society.

CONCLUSION

Indonesia's patent reforms present both opportunities and challenges as they aim to attract investment and foster innovation while also raising concerns about medicine affordability and local pharmaceutical competitiveness. Achieving a balance between incentivizing research and development (R&D) and ensuring access to essential medicines is crucial, necessitating a nuanced approach that combines regulatory flexibility with robust public health safeguards. Key strategies include implementing conditional compulsory licensing for public health emergencies, enhancing R&D incentives through tax exemptions and grants, and fostering public-private partnerships to strengthen domestic pharmaceutical capabilities. Additionally, regulatory harmonization with ASEAN strategies can facilitate regional cooperation, enhancing supply chains and reducing dependency on imported drugs. Ongoing monitoring and adaptive policy refinement through a multi-stakeholder advisory committee will be essential for aligning reforms with healthcare goals. A proactive, evidence-based policy approach will help Indonesia refine its pharmaceutical patent system, balancing innovation with equitable access to affordable medicines for its citizens. Future research should evaluate the effectiveness of conditional compulsory licensing and alternative licensing models, assess R&D incentives, and explore regional collaborations to further strengthen the pharmaceutical landscape in Indonesia.

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