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Balancing Pharmaceutical Innovation, Protection for Local Industries, and Potential Evergreening: An Analysis of Indonesia's Patent Law Amendments

Kholis Roisah [a], Rahayu Rahayu[a], Muhamad Nafi Uz Zaman [a] ✉,
Zinatul Ashiqin Zainol [b], Mohd Zamre Bin Mohd Zahir [b]

[a] Faculty of Law Universitas Diponegoro, Semarang, Indonesia
[b] Faculty of Law Universiti Kebangsaan Malaysia, Selangor, Malaysia

✉ Corresponding email: mnafiuzzaman@live.undip.ac.id

Abstract

Recent changes to the Patent Law in Indonesia have sparked discussion regarding efforts to balance pharmaceutical innovation, protection of local industries, and the potential for evergreening practices. This study is a doctrinal research that uses a multi-approach analysis to examine the interaction between these variables in the context of Patent Law Number 65 of 2024. The study draws on literature reviews, theories and concepts related to drug patents, the pharmaceutical industry, the right to affordable medicine, and the evergreening. The research also includes an analysis of relevant laws and regulations, including the Patent Law before and after the amendment, to identify the changes and the underlying legal policy. The results show that the removal of Article 4 (f) of the Patent Law, which previously excluded certain inventions as inventions, may open up opportunities for the evergreening. However, the government argues that the deletion aims to protect local pharmaceutical companies and broaden the definition of invention. This

study critically examines these claims, taking into account the readiness of the local pharmaceutical industry to compete with multinational corporations. In addition, there is a need for a strict control mechanism to ensure the validity of the invention in the patent as well as an objective evaluation of the inventive step and its therapeutic value. This study concludes that without adequate planning, the extension of patent protection to minor modifications may prolong commercial dominance of drugs, open opportunities for evergreening practices and ultimately hinder public access to essential and affordable drugs.

KEYWORDS *Pharmaceutical Innovation, Protection, Local Industry, Evergreening, Indonesian Patent Law*

Introduction

The modern pharmaceutical industry continues to innovate in improving the efficacy of medicines produced for the public amid various health challenges that are increasingly complex and diverse. The more innovations that are made, the more the pharmaceutical industry relies on patent protection as one of the intellectual property. For the pharmaceutical industry, patents are very important, as the pharmaceutical sector requires massive investment in research and development (R&D) before a drug is marketed. Through patent protection, the inventor or pharmaceutical company obtains legal protection of its technological invention rights,[1] and at the same time ensures that the pharmaceutical company can recover the costs incurred during the development process through a period of exclusivity in the market.[2] Market exclusivity, which means prohibiting others from making, producing or marketing the same drug invention without authorization, is important for pharmaceutical companies to recover the high costs and risks associated with drug development. Without the assurance of patent protection, companies are less likely to invest in the costly and lengthy process

[1] Joanna T Brougher and Audrey Ogurchak, "Patent Law Relevant to Early Drug Development," in *Early Drug Development: Bringing a Preclinical Candidate to the Clinic* (New Jersey: Wiley Online Library, 2018), 649–666, https://doi.org/10.1002/9783527801756.ch24.

[2] Claus Roland Gawel, "Patent Protection as a Key Driver for Pharmaceutical Innovation," *Pharmaceuticals Policy and Law* 18, no. 1 (2016): 45–53, https://doi.org/10.3233/PPL-160431.

of bringing a new drug to market.[3] This encourages innovation of new drugs that are more efficient in curing diseases, thereby improving the quality of life of individuals.[4]

While patents offer significant benefits regarding exclusivity and financial prospects, they also pose problems regarding the accessibility of drugs to the public. Patents on certain drugs, especially new and revolutionary ones, may result in increased drug prices as the patent-holding company has full authority over the production and distribution of the drug. High prices are one of the main factors contributing to overall healthcare costs and can limit patient access to essential medicines.[5] Therefore, Indonesia complies with international regulations set by the TRIPs (Trade-Related Aspects of Intellectual Property Rights) Agreement,[6] which imposes a 20-year limitation on the duration of patent protection for medicines, as well as allowing the production of generic medicines after the patent expires.[7]

However, in practice, the validity period of patent protection can be extended by utilizing legal loophole exploitation in domestic regulations, even if there is no invention, only minor changes to the formulation or packaging. Pharmaceutical companies use strategies such as combinations, new medical uses, new formulations, or minor changes to existing drugs to extend their patents. Such a practice in the pharmaceutical industry is often known as evergreening.[8] This practice is often criticized for delaying the entry of generics and maintaining high prices of pharmaceutical products.

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3 Iain Cockburn and Genia Long, "The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals," *Expert Opin Ther Pat* 25, no. 7 (2015): 739–42, https://doi.org/10.1517/13543776.2015.1040762.

4 Valentino M Demmassabu, "Penghapusan Lisensi Paten Oleh Pemegang Hak Paten Menurut UndangUndang Nomor 13 Tahun 2016 Tentang Paten," *Lex Privatum Jurnal* 5, no. 2 (2017), https://ejournal.unsrat.ac.id/index.php/lexprivatum/article/view/15279.

5 Shimeng Qu, "An Economic Analysis of Cancer Drug Pricing: Market Failures, Policy Challenges, and Equity Implications," *International Journal of Innovative Research and Scientific Studies* 8, no. 4 (2025): 500–506, https://doi.org/10.53894/ijirss.v8i4.7877.

6 M. J. C. Geofrey, and K. Roisah, "Patenting Deal in Indonesia, Article 20 of The Patent Law in The Political Perspective of International Trade Law," LAW REFORM, vol. 16, no. 1, pp. 19-31, Mar. 2020. https://doi.org/10.14710/lr.v16i1.30302

7 Triayu Ratna Dewi and Erma Defiana Putriyanti, "Melindungi Sumber Daya Genetik Dan Pengetahuan Tradisional Dengan Hak Paten Dan Hak Merek," *Populis : Jurnal Sosial Dan Humaniora* 4, no. 2 (2021): 337–45, https://doi.org/10.47313/pjsh.v4i2.697.

8 Inderjit Singh Bansal et al., "Evergreening - A Controversial Issue in Pharma Milieu," *Journal Inttelectual Property Rights* 14 (2009): 299–306.

Pharmaceutical companies will capitalize as long as the patent protection period can be extended.[9]

The practice of evergreening is done to obtain a new patent against an already patented invention by incorporating advancements, modifications, or other elements that qualify as a new invention. Although listed as inventions through new patent applications, these filings often lack true innovation or novelty. They may not show an inventive step or consist only of simple modifications without substantial improvement in efficacy.[10] This is closely related to the motives of pharmaceutical companies to extend the duration of patent monopolies and maximize and expand their revenues.

Indonesia has actually made efforts to prevent the practice of evergreening normatively through Article 4 letter (f) of Law No. 13/2016 on Patents, which contains exceptions from inventions that are not categorized as inventions. These exceptions include new uses of existing products and/or new forms of existing compounds that do not result in a significant increase in efficacy. Through this rule, pharmaceutical companies will not necessarily be able to register or extend their patents as long as they are based on inventions that are excluded by the rule. Thus, it can be said that this rule locks pharmaceutical companies from evergreening.

However, in its development after going through a long process in the legislature, the Patent Law underwent changes with the enactment of Law No. 65 of 2024, one of which was to delete the provisions of Article 4 letter (f). This change raises the question of whether the deletion of Article 4 letter (f) can be an entry point for the practice of evergreening in the midst of the increasingly complex challenges of pharmaceutical security in Indonesia and what exactly is the legal policy behind the change. Based on the academic paper on the amendment of the Patent Law, it can be indicated that the legislators wanted to expand the definition of invention itself, by removing the provision on excluded inventions. Meanwhile, the legal policy that can be read is that Indonesia will indeed focus on the existence of pharmaceutical

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[9] Say-yed Hesameddin Tafreshi, "Anti Pharmaceutical Patent Ever-Greening Law: Global Need in Support of Public Health," *Journal of Intellectual Property Rights* 24, no. 3-4 (201AD): 103–112, http://nopr.niscpr.res.in/handle/123456789/54174.

[10] John R Thomas, *Patent "Evergreening": Issues in Innovation and Competition* (Congressional Research Service, 2009), https://doi.org/http://dx.doi.org/10.2139/ssrn.5156845.

companies, and not examine further how to fulfill the right of public access to affordable drugs. Thus, things that hinder this existence are abolished.[11]

At first glance, the government's position seems to favor the pharmaceutical industry over the public in reaching medicines. However, other arguments from the government can also be understood when based on the reality that occurs in the local pharmaceutical industry, where so far the development of the local pharmaceutical industry is still at the stage of formulating drugs, packaging and distribution, but not enough to produce new drugs. [12]The reason is that the industry is still dependent on imported raw materials, limited mastery of technology, and low research and development costs.[13] The fact is that various drug patents registered in Indonesia are still held by large global pharmaceutical companies, which have substantial market power and control most pharmaceutical patents worldwide.[14] On the other hand, the need and availability of affordable drugs for the community must also be considered by the government. Therefore, they consider that if the invention tap in the Patent Law is further opened, more local pharmaceutical industries will be able to produce their own drugs.

Studies on drug patents and evergreening practices are actually quite common in global literature.[15] For example, Jeldine Adite and Pettersson evaluated how the European Union (EU) patent system deals with evergreening practices in the pharmaceutical industry.[16] Furthermore, Beerannavar and Koshi highlighted how evergreening raises concerns about access to affordable medicines, especially in developing countries such as

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[11] Badan Pembinaan Hukum Nasional, "Naskah Akademik Rancangan Undang-Undang Tentang Perubahan Kedua Atas Undang-Undang Republik Indonesia Nomor 13 Tahun 2016 Tentang Paten 2022" (Jakarta, 2022).

[12] Kholis Roisah, Rahayu, and Diaz Rachmanda, "The Working Patent and Pharmaceutical Industry Development in Indonesia," *Review of Economics and Finance* 21, no. 1 (2023): 304–315, https://doi.org/10.55365/1923.x2023.21.29.

[13] Ria C Siagian et al., "Assessment of Country Readiness for Drug Development: A Qualitative Study in Indonesia," *World Medical and Health Policy* 13, no. 4 (2021): 728–748, https://doi.org/10.1002/wmh3.440.

[14] Andre Marc Gagnon, "The Anatomy of Big Pharma," in *The Routledge Handbook of the Political Economy of Health and Healthcare* (London: Taylor and Francis, 2024), 245-258, https://doi.org/10.4324/9781003017110-23.

[15] Reed F Beall et al., "Patent 'Evergreening' of Medicine–Device Combination Products: A Global Perspective," *Health Policy* 18, no. 2 (2022): 14–26, https://doi.org/10.12927/hcpol.2022.26973.

[16] Louise Pettersson and Jeldine Adite, "Evergreening in the Pharmaceutical Industry: How Viable Is Evergreening for Sustaining Competitive Advantage within the Pharmaceutical Industry in the EU?" (Uppsala Universitet, 2025), https://www.diva-portal.org/smash/record.jsf?pid=diva2%3A1981324&dswid=-8085.

India, where high drug prices have an impact on public health.[17] In this case, the government must intervene against monopolies that cause huge financial losses to patients.[18] A number of recent studies still need to be further examined, especially in practice in Indonesia, because there are other variables, namely the recent changes to the Patent Law and the development of the local pharmaceutical industry. This research is limited to a general discussion of drug patents and evergreening in the 2016 Patent Law.[19] A study discussing the specific impact of evergreening on access to medicines in Indonesia was conducted by Agung Prakoso,[20] which certainly needs to be elaborated, particularly regarding the development of the local pharmaceutical industry.

This dialectic is certainly interesting to be studied further on how the government must balance various variables between innovation in the pharmaceutical, the resilience or existence of the local pharmaceutical industry and the guarantee of the right to access affordable drugs. On the one hand, protection of inventions is still needed to encourage investment and innovation in the pharmaceutical industry. But on the other hand, when patents actually cause obstacles to access to medicines for the community, the state is present through proportional intervention. This means that a balance between these variables must be realized to create an equitable pharmaceutical industry ecosystem.

This paper is a multi-approach study that analyzes several variables, namely innovation in pharmacy itself, the resilience of the local pharmaceutical industry, the right to access affordable medicines and the potential for evergreening practices after changes to the Patent Law in Indonesia. This study is new, because it is not only a discussion after the amendment to the Patent Law in 2024, but also a dialectic between variables to determine how an equitable pharmaceutical industry ecosystem will look

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[17] Chaitra Rangappa Beerannavar and Sandra Mariya Koshi, "Regulatory and Strategic Challenges of Patent Evergreening in the MedTech Industry: An Analysis of Competition Law Implications," in *Strategic Management, Regulatory Challenges, and Global Governance of MedTech* (London and Beijing: IGI Global Scientific Publishing, 2025), 149–84, https://doi.org/10.4018/979-8-3373-1205-7.ch007.

[18] Jishian Ravinthiran, "Using The Inflation Reduction Act to Rein in Patenting & Evergreening Abuses" (Washington D.C, 2024), https://www.citizen.org/article/using-the-inflation-reduction-act-to-rein-in-patenting-evergreening-abuses/.

[19] Metya Mutiara Cahyani, "Analisis Yuridis Praktik Patent Evergreening Pada Invensi Obat-Obatan Di Industri Farmasi Berdasarkan Undang-Undang Nomor 13 Tahun 2016 Tentang Paten Di Indonesia" (Universitas Negeri Sebelas Maret, 2023).

[20] Agung Prakoso, "Membongkar Praktik Patent Evergreening Terhadap Akses Obat" (Jakarta, 2023), https://igj.or.id/2023/08/07/membongkar-praktik-patent-evergreening-terhadap-akses-obat/.

like. This paper broadly discusses two things, namely the legal policy of changes to the Patent Law: between opening up the practice of evergreening or protecting local pharmaceutical companies and the implications of changes to the Patent Law on the elimination of inventions that are excluded as inventions on the right to public access to affordable medicines.

This paper is the result of a doctrinal research based on a literature study approach using various literatures as well as an understanding of theories and concepts[21] about drug patents, the pharmaceutical industry, the right to affordable drugs and the practice of evergreening. Legislative studies are also used, especially those governing the Patent Law both before and after the amendment. The aim is to see the differences as well as the legal policy of the changes. In addition, international legal instruments on patents such as TRIPs and its development are also used to see the extent of the existence of drug patents and their practices in other countries. The data collected was also verified through interviews with relevant stakeholders such as the Food and Drug Monitoring Agency (hereinafter BPOM) and the Directorate of Intellectual Property of the Indonesian Ministry of Law. The purpose of the interviews was to verify secondary legal materials and explore policies within both institutions. All data, both secondary legal materials and interview results, were integrated and analyzed, and conclusions drawn based on the research question were drawn.

Legal Policy of Patent Law Amendment: Between Opening the Practice of Evergreening or Protecting Local Pharmaceutical Companies?

Historically, the Indonesian Patent Law has undergone a number of changes, starting from Law No. 6 of 1989, Law No. 13 of 1997, Law No. 14 of 2001, Law No. 13 of 2016, to the latest, Law 65 of 2024. These changes were intended to adjust to the development of global dynamics as well as Indonesia's international commitments such as the TRIPs Agreement and national needs, including the protection of local inventions. However, in the latest amendment, a dialectic emerged about the political direction of the law underlying the abolition of Article 4 letter (f) on findings that are excluded as inventions. The discussion focused on the question of whether the amendment opened a loophole for the practice of evergreening, which was

[21] V. H. S. Budi, M. Girodon-Hutagalung, and J. Irawati, "Integrating IPR Integrity and Freedom of Expression: A Normative Analysis," *Law Reform* 20, no. 1 (2024): 153-169. https://doi.org/10.14710/lr.v20i1.62089

carried out as a strategy to extend the patent period through small claims for new forms of old drugs, or was aimed at strengthening the capacity of the local pharmaceutical industry to compete and be independent.

This debate arises because there are articles that are considered to weaken the principle of novelty of invention and expand the definition of patents, which can be utilized by multinational companies to maintain market dominance. Meanwhile, the government argues that the changes aim to facilitate access to technology for domestic industries, encourage technology transfer, and accelerate the growth of local inventions.[22] Therefore, it is important to further examine whether the changes in the substance of the Patent Law actually support the strengthening of the local innovation ecosystem and public access to medicine, or instead accommodate the interests of the global market in a way that can hinder national pharmaceutical independence.

A. Evergreening Practices in Drug Patents

Evergreening is a term that refers to a number of ways used by patent owners of pharmaceutical products to extend their monopoly rights to drugs, which are generally drugs that have high profits (so-called blockbuster drugs, which are drugs capable of generating revenues of more than 1 billion dollars per year).[23] A number of ways are sought in the form of minor changes or revisions, such as reformulations, new dosages, new combinations, new variations or forms, methods of administration or even therapeutics in different conditions, to previously patented drugs.[24] This evergreening can extend the monopoly rights to the drug for twenty years.[25] While not unlawful, this strategy appears to undermine the very essence of patent law.[26]

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[22] A. Sujatmiko, M. K. Romadhona, and Y. R. Saraswati, "Patents at the Crossroads: Legal Pathways for Advancing Technology Transfer in Indonesia," LAW REFORM, vol. 21, no. 1, pp. 94-119, Mar. 2025. https://doi.org/10.14710/lr.v21i1.64666

[23] Thomas A Faunce and Joel Lexchin, "'Linkage' Pharmaceutical Evergreening in Canada and Australia," *Australia and New Zealand Health Policy* 4, no. 1 (December 1, 2007): 8, https://doi.org/10.1186/1743-8462-4-8.

[24] Joy K L Andrade et al., "Evergreening of Psychiatric Medications: A Systemic Literature Review of Strategies, Case Examples, and the Implications of Cost," *Community Mental Health Journal* 59, no. 3 (2023): 451–458, https://doi.org/10.1007/s10597-022-01022-9.

[25] Asia IP, "What Is Patent Evergreening," *Asia IP*, September 27, 2024, https://asiaiplaw.com/section/in-depth/what-is-patent-evergreening.

[26] Gaurav Dwivedi et al., "Evergreening: A Deceptive Device in Patent Rights," *Technology in Society* 32, no. 4 (2010): 324–30, https://doi.org/10.1016/j.techsoc.2010.10.009; Pranali P. Paradkar, "Understanding Evergreening of Patents in the Pharmaceutical

The granting of patents for incremental changes is often used as a strategic effort to inhibit generic competition, thereby delaying the entry of lower-priced drugs into the market.[27] Patented drugs that expire and enter the generic market will eventually experience a price reduction of up to one-fifth of their original price. For example, sales of Bristol-Myers Squibb's drug Capoten dropped from 146 million dollars to 25 million dollars within 12 months of its patent expiration in the United States.[28]

Therefore, it is important for pharmaceutical companies to extend their patent periods as long as possible to maintain the profitability of their drugs. An investigation by the European Commission found that patent-holding pharmaceutical companies have devised and implemented a number of strategies, called tool-box instruments, to ensure that the revenue stream from their medicines is maintained. The strategies include filing up to 1,300 patents across the EU for one particular type of drug (patent clusters), engaging in disputes with generic companies for up to 700 reported patent litigation cases, entering into settlement agreements with generic drug companies that could potentially delay the launch of generics and intervening in national procedures for generic drug approval.[29]

This practice of evergreening has been practiced by the company Novartis in South Africa which obtained a patent in 1993 on the drug imatinib, which is used in the treatment of chronic myeloid leukemia and marketed under the name Gleevec. Before the patent on the drug expired in 2013, Novartis managed to obtain two additional patents: one in 1997 for modification of the compound form and another in 2002 related to the use of the drug in the treatment of HIV-related infections. As a result, Novartis has patent protection on the drug until 2022, or for 29 years after the first patent was granted. In contrast, in India, where the country's patent laws prohibit the practice of evergreening, the secondary patent on imatinib does not apply. The drug is available in generic form at a price 91% cheaper than the South African version.[30]

Industry," *Journal of Chemical Health Risks* 9, no. 2 (2019): 173-75, https://jchr.org/index.php/JCHR/article/view/8397/4799.

[27] Nina Yin, "Pharmaceuticals, Incremental Innovation and Market Exclusivity," *International Journal of Industrial Organization* 87 (2023), https://doi.org/10.1016/j.ijindorg.2023.102922.

[28] Dwivedi et al., "Evergreening: A Deceptive Device in Patent Rights."

[29] Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (Switzerland: The South Center, 2000).

[30] Fran Quigley, *Prescription for the People* (New York: Cornell University Press, 2017).

The International Covenant on Economic, Social and Cultural Rights (ICESCR) states that evergreening can be a major obstacle to the fulfillment of the right to health. Delays in bringing lower-priced medicines to market can result in a huge increase in costs for public health budgets.[31] In 2019, Americans are expected to spend 3.8 trillion dollars on healthcare, including 511 billion dollars on pharmaceutical products.[32] This is because the high price of medicines is a financial burden for Americans who need access to certain medicines.[33]

While some argue that evergreening encourages continuous innovation, many criticize that the practice takes the focus away from developing innovative new drugs, as companies will focus more on modifying existing drugs rather than investing in research and development of new drugs. Through evergreening, even most of the new chemical entities patented by pharmaceutical companies do not add value to medicine. Researchers estimate that as much as 70 percent of new drugs marketed do not provide additional therapeutics value and only a few drugs actually provide the benefits of therapeutics innovation.[34] Similarly, a 2009 European Commission study found that 87% of newly granted or pending drug patents in EU countries were secondary patents, most likely for the purpose of evergreening.

Due to the practice of evergreening, several countries have implemented mechanisms to prevent or reduce the impact of evergreening, such as in Canada and Australia which impose Linkage Provisions, the creation of a drug regulatory body in Canada in the form of the Office of Patented Medicines and Liaison, as well as in Australia tightening patent application requirements,[35] and other mechanisms in the form of developing stricter patent criteria, limiting the practice of evergreening, and encouraging generic competition.

The practice of evergreening in the world is carried out through various motives, at least the three common motives are as follows:

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[31] Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries.*

[32] McKenzie E. List, "The Hollow Rhetorical of Evergreening," *Jurimetrics: The Journal of Law, Science & Technology* 61, no. 4 (2021): 495–522, https://www.jstor.org/stable/27190062.

[33] List, "The Hollow Rhetorical of Evergreening," 2021.

[34] Quigley, *Prescription for the People.*

[35] Stephanie Crosbie, "The Limited Impact of Evergreening Practices in Australia," *Journal of Law, Information and Science* 23, no. 2 (2014): 83–105, https://search.informit.org/doi/10.3316/informit.255257203681813.

1) Patent Thickening: Registering related patents (e.g., manufacturing process, formulation, or new indication) for the same product.
2) Patent Extension: Obtaining patent extensions by claiming minor innovations, such as changes in dosage or drug combinations.
3) Licensing Agreements: Agreements with generic manufacturers to delay the launch of their products.

The patent protection process for pharmaceutical products begins with the initial patenting or discovery of a new drug molecule. During this phase, the drug patent will be granted for a period of 20 years. Shortly before the patent protection period expires, pharmaceutical companies apply for modifications that will extend the validity of the patent. The changes applied for may not be very significant, lack innovation, not constitute an inventive step, or fail to improve clinical benefits. Upon approval of the second or third patent and subsequent patents, an extended period of patent protection is granted for the application. The duration of comprehensive patent protection for the drug may eventually exceed 20 years

Cases of evergreening also occur in Indonesia. The practice is often hidden in complex business operations, with regulatory conditions that allow patent extension through legal loopholes. A simple example can be seen in the case of Indonesia's patent on the compound sofosbuvir (and its derivatives).

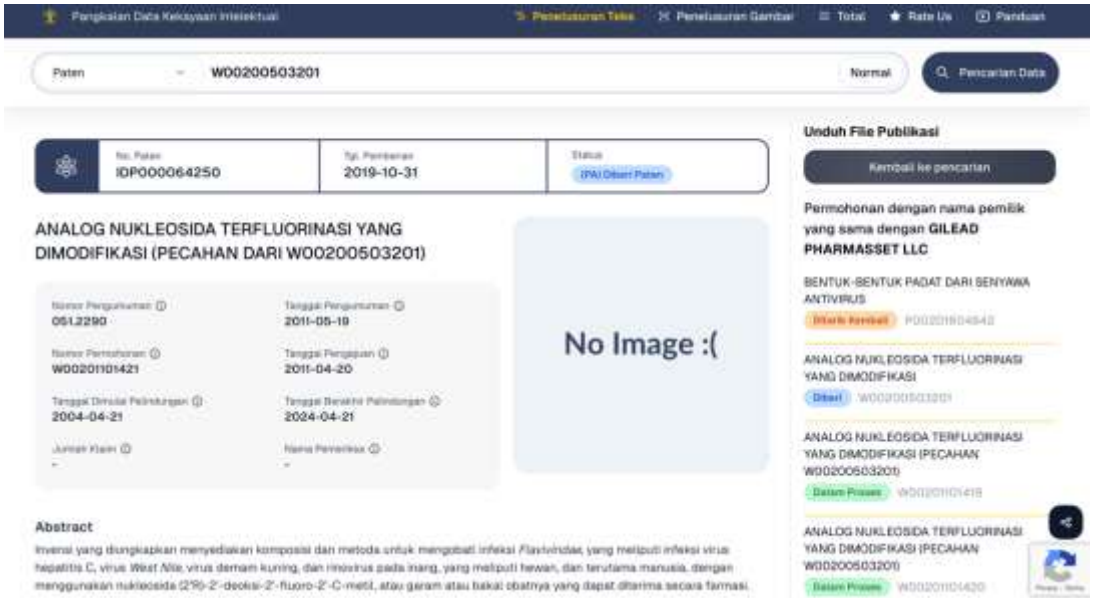

FIGURE 1. Indonesian Intellectual Property Database

The patent on the Sofosbuvir drug for Hepatitis C was first registered in Indonesia with patent number IDP000028288 or application number W00200503201. This patent is titled 'Modified Fluorinated Nucleoside Analogs', which was registered on April 21, 2004, and is scheduled to expire

on April 21, 2024. However, by examining the above graph, it is evident that many patents were registered thereafter. The latest patent was registered under application number PP00201504713 and has been issued patent number IDP000052742. This patent application is titled 'Formulation of Combination of Two Antiviral Compounds'. This application was registered at on July 30, 2015, and its protection will expire on July 30, 2034. The patent for Sofosbuvir has been extended for 10 years from its original term. The patent holder of Sofosbuvir is the pharmaceutical company Gilead.

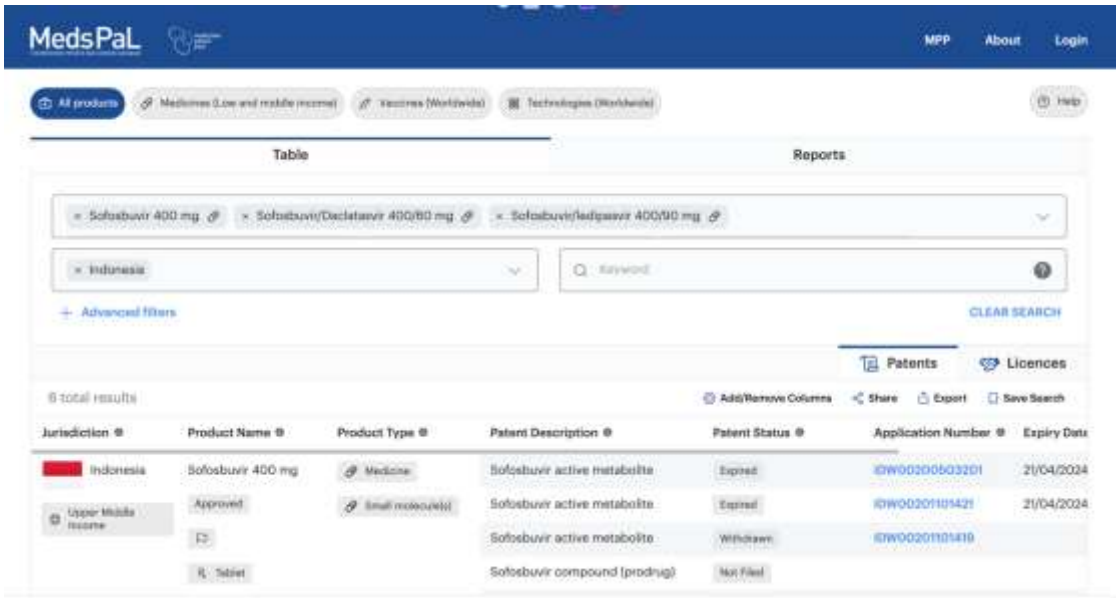

FIGURE 2. MedsPaL data (The Medicines Patents and Licenses Database)

The data mentioned above is an empirical fact that occurs in Indonesia regarding the practice of evergreening. The practice has been rejected by the public in Indonesia since 2015. Ayu Oktariani, the petitioner of the cheap hepatitis drug Sofosbuvir on the change.org page, submitted a petition that had been supported by 3,300 signatures to the Ministry of Health. To commemorate World Hepatitis Day, the *Koalisi Obat Murah* (KOM) held a peaceful rally. KOM, which consists of a combination of patient groups, individuals and civil society organizations, visited the offices of the Food and Drug Monitoring Agency (BPOM) and the Ministry of Health. In her petition, Ayu estimated that seven million Indonesians are infected with hepatitis C, and 20 percent of them need treatment because hepatitis C in the body will develop into chronic and cause cirrhosis and death. However, Ayu, who is HIV-positive and also hepatitis C positive, said it is not easy to get hepatitis medication because of the high price, making it inaccessible. According to Ayu, in contrast to Pegylated Interferon, which is injected, Sofosbuvir, which is swallowed orally, has been proven to have minimal side

effects for patients who consume it and a higher success rate. Ayu said the price of Sofosbuvir in India, Pakistan and Egypt reaches Rp3 million per bottle, while the patent medicine reaches Rp365 million per bottle.[36]

Based on the empirical data both practice evegreening in Sofosbuvir and hepatitis C medicine, indicates a far cry from the spirit of providing easy public access to widely needed medicines. This is further reinforced by the third amendment to the Patent Law, Law Number 65 of 2024 concerning the Third Amendment to Law Number 13 of 2016 concerning Patents. The significant change made by Indonesia, in the context of this research, was the removal of the article containing regulations on preventing evergreening practices. Article 4 (f) of the 2016 Patent Law was removed in the 2024 amendment to the Patent Law.

B. Legal Policy of the Patent Law Amendment

Reading the legal policy of a law can be analyzed through how the policy direction of the legislator is manifested through the study of academic papers. Based on the study of the academic paper, there have been three amendments to the 2016 Patent Law which are intended to follow global developments and the needs of the community,[37] as follows:

1) Law No. 13 of 2016 on Patents, as the main law on Patents which is actually also a refinement of the previous Patent Laws, including Law No. 14 of 2001, Law No. 13 of 1997 and Law No. 6 of 1989 on Patents).
2) Law No. 1l of 2020 on Job Creation (as the first amendment which in essence is a law amended through the omnibus law method with the aim of deregulation and increased investment, including patent provisions. However, this law was formally tested and canceled through Constitutional Court Decision Number 91/PUU-XVIII/202, because it did not go through a *meaningful participation* process.
3) Law Number 5 of 2023 on the Stipulation of Government Regulation in Lieu of Law Number 2 of 2020 on Job Creation into Law. (as the second amendment which is actually substantially the same as the first amendment, but only different in format or legal product)

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[36] Dewanto Samodro, "Petisi Obat Hepatitis Murah Diserahkan Ke Kemenkes. ANTARA News," *ANTARA News*, July 28, 2015, https://www.antaranews.com/berita/509179/petisi-obat-hepatitis-murah.

[37] Luluk Indarinul Mufidah and Mukhamat Saini, "Perlindungan Dan Permasalahan Hukum Bagi Pemegang Hak Paten Di Indonesia," Kartika: Jurnal Studi Keislaman 3, no. 1 (2023): 61–71, https://doi.org/10.59240/kjsk.v3i1.34.

4) Law Number 65 of 2024 on the Third Amendment to the Patent Law 2016 - hereinafter referred to as the Patent Law 2024 (the changes in this law can be said to be quite numerous with a total of 49 changes).

The discussion on the third amendment to the Patent Law has actually been carried out for a long time. The academic paper has been available since 2019, although it has undergone various changes. One of the provisions deleted and discussed in this paper is the provision of Article 4 letter f. The deleted provision is as follows:

> *"Invention does not include: f. discovery in the form of*
> 1. *a new use for an existing and/or known product; and/or*
> 2. *a new form of an existing compound that does not result in a significant increase in efficacy and there is a difference in the related chemical structure that is already known from the senvawa."*

Through these changes, inventions usually made by pharmaceutical companies can be registered as new patents even if the invention is derived from an existing compound or just a new use. Previously in the 2016 Patent Law , inventions that did not result in a significant increase in efficacy or even minor modifications could not get patent protection. For example, there is a compound ABC for which a patent was registered to treat diabetes. Later, the ABC compound was developed by the inventor through a lengthy research and development process, resulting in the discovery of new uses such as for hypertension. The point is that although the compound is the same, namely ABC, there is a new use (second medical use) and produces a different effect than before, so that it will produce two different patents, namely the ABC compound for diabetes, and the ABC compound for hypertension.

If traced in the academic paper, in general, the government wants to emphasize on two main points, namely first, restoring the concept of patents that recognize all types of inventions without any limitations or exceptions to certain inventions, and second, the development of the local pharmaceutical industry whose movement has been limited due to the exclusion of inventions that are not recognized as inventions in the old patent law.

The first is the affirmation of the concept of patents, especially for drug patents that do not limit certain inventions. This means that any invention that produces an invention, even if it does not produce efficacy or only a minor form of modification, should still be included in patent protection. This is in line with the application of Swiss type claims which is recognized and carried out in WIPO practice, as well as recognized for its usefulness by

several countries that have pharmaceutical industries, such as Europe, the UK and New Zealand. The Swiss Type Claim concept allows the development of certain products for specific purposes, for example the use of compound X in the manufacture of a medicament for the treatment of disease Y *"use of substance X in the manufacture of a medicament for the treatment of disease Y".* Through this format, protection is not given to the substance itself (because it is already known), but to the new medical purpose of its use.[38] Although in its development, many critics stated that Swiss type claims are illegal.[39]

The exclusion of findings that are not included as inventions in the 2016 Patent Law can also actually be said to be a form of legal choice or implementation of the flexibility chosen by Indonesia. Because TRIPs only determines the minimum standards for the implementation of IPR in each country.[40] This means that when referring to the provisions of TRIPs, there is actually no further explanation of what is not included in the invention. The provisions in TRIPS define patents shall be available for any invention, whether product or process, in all fields of technology, provided that it is new, involves an inventive step and is capable of industrial application. (article 27(1) TRIPs). The exceptions expressly mentioned in article 27(2) of TRIPs relate only to the prevention within their territory of commercial exploitation necessary for the protection of public order or morality, including for the protection of human, animal or plant life or health or for the avoidance of serious prejudice to the environment, provided that the exceptions are not made solely because the exploitation is prohibited by their laws.

TRIPs also gives countries the opportunity to exclude patents, including:

a. diagnostic, therapeutic, and surgical methods for the treatment of humans or animals;
b. plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

Based on all these exclusion provisions in TRIPs, there is no provision for limitation of inventions as stipulated in the Patent Law 2016. In addition to the issue of exclusion of findings, the step of removing these provisions is

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[38] Beatrice Holtz and Lionel Vial, "A Brief History of Swiss Type Claims," *Managing Intelletual Prop* 180, no. 82 (2008).

[39] Daniel Armstrong, "The Arguments of Law, Policy and Practice Against Swiss-Type Patent Claims," *Victoria University of Wellington Law Review* 32, no. 1 (2001): 253–54, https://doi.org/10.26686/vuwlr.v32i1.5910.

[40] Safril Sofwan Sanib, "Ketentuan-Ketentuan TRIPS-Plus Dalam Kerangka Perjanjian Perdagangan Bebas," *Halu Oleo Law Review* 3, no. 1 (2019): 50, https://doi.org/http://dx.doi.org/10.33561/holrev.v3i1.6016.

also intended to reward the research and development (RnD) process which is long and certainly requires investment costs, so that it is rewarded.

Secondly, the development of the local pharmaceutical industry is based on all findings either new uses or the results of the utilization of pre-existing drug compounds. This is because the main problem with the provisions of the 2016 Patent Law is that the local pharmaceutical industry is "locked" in its movement not as the main drug producer, but only as a distributor or an industry that only makes the packaging of the drug. The reason is that the exclusion of inventions that are not categorized as inventions inhibits the exploration of the utilization and development of existing drugs, especially for the development of drugs derived from Indonesia's rich genetic resources. Drugs that are already commonly circulated are already controlled by global companies with a large scale of production. Meanwhile, local pharmaceutical companies cannot develop or formulate drugs because they are hindered by the exception found in Article 4 letter f.

In the previous provision, any drug development by local pharmaceutical companies only stopped at inventions that could not be patented and were not incentivized, so local pharmaceutical companies preferred to engage in distribution rather than production. They consider investment in trade (selling/distribution) to be more profitable than investment in production, which usually involves research and development of existing products.

The academic paper also examines the doubts about the practice of evergreening as a result of the abolition of Article 4 letter f. Strictly speaking, the drafter of the amendment to the Patent Law stated that the elimination of the provision would not necessarily open up opportunities for evergreening practices. This is because the compounds that are registered with the efficacy of treating a disease and have expired their patents (patent-protected drug composition compounds) have indeed become public domain. However, patent applications for the same compound for the treatment of other/new diseases can still be granted patents. For example, with the same analogy as before, if compound ABC for diabetes has expired for 20 years, the specific compound and its uses have become public domain, while compound ABC used for hypertension can be applied for a new patent.

Apart from the two main points contained in the study of the academic paper on the third amendment to the Patent Law, there are major problems, especially regarding the existence of the local pharmaceutical industry today, post-Covid-19. For example, related to production disruption constraints due to limited raw materials for impo drugs, logistical distribution to each region,

to disrupted stock of goods due to very high demand.[41] The pandemic provides a reflective momentum on the importance of pharmaceutical sovereignty and resilience, which was tested at that time, especially in ensuring the availability of drugs and medical devices independently when the global supply chain is disrupted. Because through the resilience of the local pharmaceutical industry, it can affect multi-sectors, for example economic growth, fulfill the scarcity of pharmaceutical products and medical devices and reduce import dependence on raw materials for drugs and medical devices.[42]

Therefore, it is hoped that changes in patent policy can encourage innovation until the final stage, namely when drugs or pharmaceutical products can actually be utilized by the public.[43] In addition, it is also important to support the development of traditional medicines so that research results based on local biological wealth can be better utilized and become a viable and affordable alternative medicine. Opening up space for inventions based on the development of existing ingredients or compounds is actually intended to adjust to local research capabilities in Indonesia.

Currently, most domestic pharmaceutical research is still in the form of development or modification of known substances, so legal protection is needed so that the research results have commercial value and can be further developed. In addition, changes to the bolar provision in the Patent Law are also expected to increase the intensity of research into generic drug development before the patent expires, so that when the patent expires, the generic product can be immediately available in the market. This policy will have a direct impact on the availability of alternative drugs and reduce prices, so that medicines become more affordable for the public, while strengthening national pharmaceutical independence.

Implications of the Amendment to the Patent Law on the Excluded Inventions

Each change in the law must have juridical, economic, and social implications, including the elimination of excluded inventions, including

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[41] Dwi Y. Arista, Widya Lestari, and Sriwidodo, "Dampak Pandemi Covid-19 Terhadap Rantai Distribusi Bahan Obat, Dan Alat Kesehatan," *Farmaka* 20, no. 2 (2022): 104, https://doi.org/10.24198/farmaka.v20i2.38770.g18191.

[42] Dandung Ruskar et al., "Pandemi COVID-19 Sebagai Momentum Kemandirian Industri Farmasi Menuju Ketahanan Kesehatan Nasional," *PENDIPA Journal of Science Education* 5, no. 3 (2021): 300–308, https://doi.org/10.33369/pendipa.5.3.300-308.

[43] Karjoko, Lego, et al. "Patent Policy on the Pharmaceutical Sector in Indonesia." *Journal of Legal, Ethical and Regulatory Issues* 23, no. 5 (2020): 1544-0044.

pharmaceutical inventions. The juridical implications relate to the dynamics of pharmaceutical business competition between the existence of local pharmaceutical companies and multinational companies. Meanwhile, from a social and economic perspective, these changes also have implications for the price and availability of drugs, as well as determining the direction of development of the domestic pharmaceutical industry. These changes certainly have logical consequences for the implementation of patent rights in the pharmaceutical industry and the extent to which patent protection can affect public access to medicines.

A. The Right to Access Affordable Medicines in the Medicinal Patent System

The right of public access to affordable medicine is actually part of human rights as Article 25 of the Universal Declaration of Human Rights (UDHR), Article 12 (1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR), and Article 1 of the Universal Declaration on the Eradication of Hunger and Malnutrition. In essence, everyone regardless of gender and national origin is entitled to health insurance and the state is obliged to recognize the right of everyone to enjoy the highest attainable standard of physical and mental health. This means that the state is responsible for ensuring access to medicine and obtaining necessary treatment without being hampered by high costs.[44] The state is obliged to provide necessary medical services to its citizens, regardless of their ability to pay. This includes developing policies and action plans to ensure access to health services.[45] Therefore, the state must regulate the distribution and price of medicines that can be accessed by the community easily and affordably.[46]

The guarantee of access to health, especially regarding medicines, is not only about availability, but also includes aspects of affordability, quality, and sustainability.[47] The availability aspect of medicines is realized through the presence of medicines that can be accessed easily by the community, regardless

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[44] Endang Purwaningsih, *Seri Hukum Hak Kekayaan Intelektual Hukum Paten* (Bandung: Mandar Maju, 2015).

[45] Tengiz Verulava, "Access to Healthcare as a Fundamental Right or Privilege?" *Siriraj Medical Journal* 73, no. 10 (2021): 721–726, https://doi.org/10.33192/Smj.2021.92.

[46] Siti Nur Cholisa Hamid and Lidya Shery Muis, "State Responsibility in Guaranteeing Access to Essential Medicines for Public Health," *Indonesian Journal of Law and Economics Review* 19, no. 3 (2024): 2–16, https://doi.org/10.21070/ijler.v19i3.1258.

[47] Johannes et al., "Perlindungan Hukum Hak Paten Dan Keadilan Akses Obat Pasca Undang-Undang Nomor 65 Tahun 2024," *Policy and Law Journal* 2, no. 1 (2025): 25–31.

of social, regional or economic status (universal). Meanwhile, affordability is implemented through determining prices that can be accessed by the community according to standards. In addition, quality talks about the quality standards that must be met before drugs are circulated in the community. All of these dimensions are interconnected and are a requirement for the fulfillment of the right to public health. When one aspect is not fulfilled, access to medicine becomes unfair.[48] The problem is that the issue of drug availability including affordability is usually still experienced by developing countries, especially for essential drugs such as drugs for malaria, dengue fever, tuberculosis, HIV/AIDS and other diseases.[49]

The fulfillment of the right to affordable drugs will also become more complex when dealing with the drug patent system. This is because drugs under patent protection are often seen as commodities with economic value. Since the beginning, TRIPs, which is the main foundation of patents, has indeed had a tendency for capitalist industrial countries to dominate the world economy, including in terms of drug supply.[50] The result can be felt when control over drug availability and prices is vested in large global companies, often referred to as "Big Pharma".[51] These companies play an important role in the pharmaceutical industry through extensive research and development (R&D) efforts, marketing strategies and global distribution networks.

The discourse on people's right of access to affordable medicines can be traced back to the development of drug patents under the TRIPs regime that prioritizes monopoly-based exclusivity for drug manufacturing companies. The exclusivity aspect is automatically attached to drug manufacturers and prohibits other parties from producing or selling patented drugs.[52] In fact, this exclusivity has the side effect of creating an imbalance for developing countries, which do not have the resources to produce drugs. Modern global drug manufacturers are usually from rich developed countries. The impact is that when a complex patent system with all its restrictions is put in place and

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[48] WHO, "Access to Medicines and Health Products," World Health Organisatioon, 2023, https://www.who.int/our-work/access-to-medicines-and-health-products.

[49] V. J. Wirtz et al., "Essential Medicines for Universal Health Coverage," *The Lancet Global Health* 389 (2017): 403–76, https://doi.org/10.1016/S0140-6736.

[50] Purwaningsih, *Intellectual Property Law Series Patent Law.*

[51] Peter T.C. Ho, "The Pharma/Biotech Model for Drug Development: Implications for Pediatric Cancer Therapeutics," in *Pediatric Oncology* (Springer Science and Business Media Deutschland, 2022), 89-107, https://doi.org/10.1007/978-3-031-06357-2_7.

[52] Putu Ayu Sriasih Wesna, "Doha Declaration Sebagai Perlindungan Masyarakat Atas Akses Obat Esensial Di Negara Berkembang Pasca TRIPs Agreement," *Kertha Wicaksanaka* 14, no. 1 (2020): 16–22, https://doi.org/10.22225/kw.14.1.2020.56-62.

favors rich countries, it is an injustice for poor countries. They have to pay a considerable amount of money.[53]

A WHO study of several developing country populations revealed the "impoverishing" effect of buying medicines.[54] Another survey by Health Action International on the prices of several types of drugs in the world showed that to buy Ciprofloxacin Orginitator, people have to spend the equivalent of their working income for ten days.[55] For example, there is a difference in the price of the drug Flucanazole for HIV/AIDS patients, in India it costs $55, while in the Philippines it costs $697 and Indonesia $703. This fact occurs because Flucanazole in India is not protected by a patent.[56]

Based on this background, the Doha Declaration on the TRIPs Agreement and Public Health was born as a complement to TRIPs on November 14, 2001, which was fully supported by developing countries and non-governmental organizations.[57] The goal is to find a balance between the interests of patent holders, namely inventors and public health rights, especially developing and underdeveloped countries.[58] The framework used in this declaration is that public health and public access to medicines must be prioritized, because health is an essential aspect of human life.

Through the Doha Declaration, there is flexibility for countries to interpret some of the protective rules of TRIPs, which was then agreed upon changes to Article 31 through the Protocol Amenmend of The TRIPs Agreement in 2005 and came into force in December 2017 after being ratified by 2/3 of WTO member countries. The amendment regulates *compulsory licensing* more flexibly by giving the right for countries that do not have an adequate pharmaceutical industry to allow the import of generic drugs without permission from the patent holder, at a lower price than other countries. The provisions of article 31 regulate the reasons for not requiring permission from the patent holder, in the event of a national emergency or other circumstances of extreme urgency or public non-commercial use.

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[53] Lidya Shery Muis, "Hak Atas Aksesibilitas Obat Paten Bagi Masyarakat," *Pranata Hukum* 2, no. 1 (2019): 36–64, https://doi.org/10.37631/widyapranata.v1i1.259.

[54] Muis.

[55] Titon Slamet Kurnia, *Hak Atas Derajat Kesehatan Optimal Sebagai HAM Di Indonesia* (Bandung: Alumni, 2007).

[56] Alan O. Sykes, "TRIPs, Pharmaceuticals, Developing Countries and the Doha 'Solution'" (Chicago, 2002).

[57] Tomi Suryo Utomo, "Deklarasi Doha Dalam Perspektif Akses Obat Murah Dan Terjangkau: Sebuah Pelengkap Perjanjian TRIPs," *Unisia* 64 (2007): 122–32, https://doi.org/10.20885/unisia.v0i64.5684.

[58] Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries.*

Indonesia implements the amendment of Article 31 of the TRIPs Agreement through Article 93 of Patent Law Number 13 Year 2016.

B. Implications of the Elimination of Invention Provisions on the Right of the Public to Access Affordable Medicines and the Development of the Local Pharmaceutical Industry

The initial consequence of the elimination of findings that are excluded as inventions is the opening up of opportunities for drug patent registration and the wider scope. Even if it is only a modification of the use of an already registered compound, a patent can still be registered. Although in the academic paper, the legislator clearly states that the deletion of the provision does not open up opportunities for evergreening, this needs to be analyzed further. The deletion needs to be read critically within the framework of the balance between the protection of intellectual property rights and the public interest in the right to health. Therefore, reading its implications must be based on theoretical research studies and the reality of drug patent development in Indonesia.

The government's claim of increased availability of drugs and pharmaceutical products that are more affordable with the latest changes to the Patent Law, conceptually or on paper, can indeed be justified. The pharmaceutical industry will certainly have a wider opportunity to register patents for drugs produced after going through the R&D process. The fact is that the technological capabilities of the pharmaceutical industry in Indonesia are still largely limited to formulating, filling and packaging drugs. The pharmaceutical industry does not conduct activities from the beginning (basic research) to drug raw materials, but only follows post-marketing evaluation, namely developing the final product by relying on its superiority or equivalence in bioavailability/bioequivalent (BA/BE) to comparator products. In addition, the national pharmaceutical industry is more interested in meeting market needs for pharmaceutical products that are commonly needed by the public, namely the production and marketing of drugs that are off patent or hereinafter known as generic drugs.

Moreover, in the patent law, there is a bolar provision that gives rights to other/external parties (usually generic drug manufacturers) for development and testing during the patent period to prepare the production of generic

drugs as soon as the patent expires.[59] This condition has resulted in Indonesian national pharmaceutical companies not being able to compete in the patent/innovative drug market segment. In addition, the Indonesian pharmaceutical industry has not been able to achieve the discovery of new chemical entity (NCE) because there are still many obstacles faced, especially from the aspect of R&D investment costs. The high cost of R&D is related to the following three things: (i) technology; (2) new, more complex active ingredients; (3) stricter regulatory requirements in the form of preclinical and clinical trials. Moreover, Indonesia's research budget from APBN and non-APBN is still minimal, the research budget in Indonesia is only around 0.28% of the national gross domestic product (GDP) or around IDR 37.7 trillion. This research budget is still lower than other ASEAN countries such as Vietnam, Thailand and Malaysia.

However, in the past five years, the pharmaceutical industry has been transforming from a formulation industry to a research-based industry, meaning that the pharmaceutical industry is not only producing generic drugs but also gradually and specifically producing innovative drugs. Some state-owned pharmaceutical companies, domestic (hereinafter PMDN) and foreign investment (hereinafter PMA), such as Bio-Farma, have R&D and production of viral vaccines and bacterial vaccines; PT. Dexa Medica, Dexa Development Center (DDC) which conducts R&D on formulations, innovative formulations and New Drug Delivery System (NDDS) and Dexa Laboratories of Biomolecular Science (DLBS) for R&D and production of innovative products based on biomolecular science; ; Kalbe Farma has conducted R&D in the framework of technology transfer and joint-ventures including in the development of innovative and high-tech products, such as insulin analog, long acting EPO, EPO, rituximab and bevacizumab and transtuzumab; PT Kalbio Global Medika, developing highly innovative products, namely Recombinant Protein Concentrate and biosimilar products, namely Bio Better Product to meet the needs of local and international markets as well as the development of 10 (ten) commercial biotechnology product molecules; PMA joint-venture between PT. Otto Pharmaceutical Industries, Indonesia and Chong Kun Dang Pharmaceuticals, South Korea to develop anti-cancer drugs with plans for local production of anti-cancer drugs and already in production as well as a Number of Edar License (NIE) and Halal Certificate.

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[59] Raden Bagoes Prasetyo Raharjo and Kholis Roisah, "Hak Akses Kesejatan Masyarakat Terhadap Hak Paten Produk Farmasi," *Jurnal USM Law Review* 4, no. 2 (2021): 611–12, https://doi.org/10.26623/julr.v4i2.3231.

Currently, although the ability to procure drugs domestically has reached 75% for the Indonesian market, 90% of the raw materials are still imported.[60] Based on BPOM RI data in 2022, there are 13 or around 5.8% of industries that produce drug raw materials from all pharmaceutical industries in Indonesia. This shows that the local pharmaceutical industry structure can still be developed optimally. Therefore, the readiness of human resources including investment in technology and R&D processes is key in developing the local pharmaceutical industry.

In addition to the purpose of drug availability in the community, the expansion of the object of invention in drug patents is also claimed to encourage patent protection for innovations in traditional medicines or drugs made from natural ingredients that lead to standardized traditional herbal medicines (OHT) traditional medicines whose efficacy has been tested through clinical trials or called phytopharmacology.[61] In general, phytopharmaceuticals or OHT and other natural compound products are difficult to patent.[62] The reason is usually because natural compound products are considered to be part of existing natural products, so it is not successful to show significant structural changes from the original form.[63] The main obstacle is the fulfillment of the novelty standard of phytopharmacology, which has not met the element of novelty according to the 2016 Patent Law,[64] or the Patent Law before the amendment. This is because so far, phytopharmaceuticals have only focused on developing compounds or raw materials that already exist. However, through the latest Patent Law, the invention of the efficacy of traditional medicines with a certain formula standardization or the invention of a traditional medicine manufacturing process that has not existed before is accommodated in the expansion of the scope of the invention. Such inventions based on Patent Law Amendments are

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[60] Adinda Niki Kartika, "Upaya Kemandirian Bahan Baku Obat Dalam Pengembangan Industri Farmasi Di Indonesia," Jurnal BIMF 10, no. 1 (2023): 21–32.

[61] Ritu Tiwari et al., "The Dawn till Dusk of Phytopharmaceuticals," *Saudi Pharmaceutical Journal* 32, no. 11 (2024), https://doi.org/10.1016/j.jsps.2024.102185.

[62] Ankit Sahoo et al., "Prospective Challenges for Patenting and Clinical Trials of Anticancer Compounds from Natural Products: Coherent Review," *Recent Patents on Anti-Cancer Drug Discovery* 19, no. 4 (2023): 470–94, https://doi.org/10.2174/1574892818666221104113703.

[63] Charlotte Harrison, "Patenting Natural Products Just Got Harder," *Nature Biotechnol* 32 (2014), https://doi.org/10.1038/nbt0514-403a.

[64] Raymond R Tjandrawinata and Henry Soelistyo Budi, "The Legal Protection of Patents on Phytopharmaceutical Products in Indonesia: Case Studies and Theoretical Perspectives," *International Journal of Social Service and Research* 2, no. 12 (2024): 8, https://doi.org/10.46799/ijssr.v4i12.1160.

considered to fulfill the element of new development/use of existing compounds. So the assumption is that the amendment to the Patent Law further opens up opportunities for the R&D community or pharmaceutical companies developing traditional medicine innovations to obtain patents.

The development of Indonesian traditional medicine innovation to date there are 24 phytopharmaca medicinal products that are registered at BPOM and based on the Decree of the Minister of Health Number HK.01.07 / MENKES / 1163 / 2022 concerning the National Phytopharmaca Formulary, phytopharmaca products can be used in health care facilities. As for OHT, the innovation is carried out through pre-requisite quality standards for clinical trials of herbal raw materials to be used in the production of traditional medicines under the control of the Indonesian Herbal Pharmacopoeia. The Ministry of Health until 2022 has issued Supplement I of the Indonesian Herbal Pharmacopoeia Edition II containing 110 monographs of simplisia and extracts from 55 new plants that have been tested and standardized as traditional medicinal raw materials. This is in line with the data on traditional medicine patents granted from local applicants from year to year has increased significantly. In 2025, 178 out of 425 traditional medicine inventions from within the country were granted patents and the rest came from several outside inventions (DJKI Database, 2025). This number comes from the R&D community of universities/research institutes and local pharmaceutical companies and this number dominates or beats the acquisition of traditional medicine patents from foreign applicants.

The government's claim that it wants to advance the local pharmaceutical industry to be able to produce drugs based on research and clinical trials (not just packaging and distributors) must also be followed by checking the infrastructure and production capacity and capabilities of the local pharmaceutical industry. If the government and the local pharmaceutical industry have not been able to answer this readiness, then the broad opportunities accommodated through the amendment to the 2024 Patent Law will actually be utilized by multinational pharmaceutical companies. They will be far more capitalized with technological capacity, production and R&D resources that are far greater than the local industry. This unbalanced competition is increasingly causing the local industry to be unable to develop.

In this case, government policies need to be directed at improving pharmaceutical technological capabilities, political feasibility, and innovation incentives that correlate with pharmaceutical capabilities are the main catalysts

in encouraging drug development.[65] These policies include improving technological mastery, increasing R&D budgets as government support through funding and resources dedicated to pharmaceutical research and development. Incentivizing innovation such as providing tax incentives, subsidies, and other financial support to encourage innovation and reduce dependence on imported raw materials. Creating regulations to facilitate drug development and the entry of new (innovative) drugs into the market.[66] Policies that encourage local working patents with partnerships or collaborations between the local pharmaceutical industry and multinational pharmaceutical companies that own registered pharmaceutical patents in Indonesia are one solution to avoid competition and even open up technology transfer opportunities, promoting the use of advanced technology in the development of innovative drugs.[67]

Opportunities for the development of the pharmaceutical industry also include investment in the development of biotechnology-based medicinal raw materials by utilizing Indonesia's abundant biodiversity. The market potential of traditional medicine is very broad considering that Indonesian people have a tradition of consuming traditional medicine to maintain their health. This is evident from the fact that the number of traditional medicines that have obtained distribution permits from BPOM is 24.956, which is higher than the number of chemical drugs, which is only 15.937. (BPOM data as of June 2025). Therefore, the development of innovative traditional medicines (based on research and clinical trials) can not only improve the degree of public health, longer life expectancy and at the same time can increase the availability of more efficacious drugs from the original biological resources of the Indonesian people themselves.

In addition to the point about readiness, the government's claim that the practice of evergreening will not be opened as a result of changes to the Patent Law can also be given a critical note. The reason is that minor modifications to existing compounds can be registered as patents, certainly opening up opportunities for patent holders, especially for large multinational companies to increasingly produce. They will be more concerned with minor

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[65] R. C Siagian et al., "A Policy-Making Strategy to Forecast Outcomes of Drug Development in Indonesia," *International Journal of Health Governance* 25, no. 2 (2020): 137–149, https://doi.org/10.1108/IJHG-12-2019-0083.

[66] Siagian et al., "Assessment of Country Readiness for Drug Development: A Qualitative Study in Indonesia."

[67] Erwan Hermawan et al., "Challenges And Policy Supports In Indonesian Pharmaceutical Raw Materials Industry," *Indonesian Journal of Health Administration* 11, no. 2 (2023): 196–211, https://doi.org/10.20473/jaki.v11i2.2023.196-211.

modifications for the sake of economic interests rather than researching the innovation itself, which requires more time and money, so that the innovation that is the basis of the patent cannot be achieved.

The point here is about how the government or in this case the the Directorate of Intellectual Property of the Indonesian Ministry of Law as the competent authority in patent examination matters, has a strict control mechanism for patent validity, including an objective and transparent evaluation of the substance of the invention and its therapeutic value. Applicants must prove that the drug to be registered has efficacy that meets drug invention standards, so that the burden of proof shifts to the applicant, to demonstrate their innovation. Do they have standards derived from the indicators of "new use" or "new form of an existing compound", to what extent the meaning of novelty of the invention of both the same and different compounds can be registered. All these questions can be answered when strict control mechanisms are in place. This means that without strict regulatory safeguards, the opening of patent space for minor inventions could actually prolong commercial dominance of medicines, slow the entry of generic drugs into the market, and ultimately hamper public access to affordable and essential medicines.

Conclusion

Recent changes to Indonesia's Patent Law, which removed the provision of excluding certain inventions from the category of invention, has raised questions regarding its impact on pharmaceutical innovation, protection of local industries, availability of innovative drugs, and potential evergreening practices. These changes aim to broaden the definition of invention as well as protect local pharmaceutical companies by allowing them to patent new uses or new forms of existing compounds. However, there are concerns that these changes could open up opportunities for evergreening practices by multinational pharmaceutical companies, which could extend their patent monopolies and delay the entry of affordable generic drugs into the market. The government argues that these amendments are necessary to encourage innovation and strengthen the capacity of the local pharmaceutical industry, but critics fear that without strict regulatory safeguards, this policy could lead to unfair competition and hamper public access to innovative medicines. The impact of this policy change will depend on the readiness of local pharmaceutical companies to innovate and produce drugs on a large scale, as well as the government's ability to implement effective control mechanisms to ensure patent validity and transparency. To address these potential risks while

maintaining a balance between innovation and public access, the government must consider complementary policy instruments that safeguard public health interests, like using Compulsory Licensing for public health crises, citing the TRIPs-Doha Declaration framework as the ultimate state intervention tool.

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In a just society, the right to health is guaranteed to all people, not just those who can afford it.

— **Dr. Margaret Chan**, former Director-General of the World Health Organization (WHO)

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Generative AI Statement

None

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