

Legal Protection of Patent Rights in The Pharmaceutical Industry Concerning the Availability and Accessibility of Medications in Society

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ABSTRACT

This study aims to analyze the legal protection of patent rights in the pharmaceutical industry and its implications for the availability and accessibility of medicines in the community. The research method used is normative legal research. The results show that the legal system in Indonesia has accommodated these balancing efforts through various mechanisms, such as compulsory licensing, government use of patents, and provisions in international agreements such as the TRIPS Agreement, which provide flexibility for countries under certain conditions. However, the implementation of these policies still faces various obstacles, both from regulatory and institutional aspects, as well as global pressures. These mechanisms allow countries to ensure the availability of affordable medicines for the community under certain conditions without having to completely ignore the rights of patent holders. In conclusion, legal protection of patent rights in the pharmaceutical industry must be implemented proportionally while still considering the public's right to health. Therefore, it is necessary to optimize the government's role in implementing policies that can ensure the availability and accessibility of medicines fairly, without hindering innovation in the pharmaceutical sector.

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1. INTRODUCTION

The pharmaceutical industry constitutes a sector holding a paramount role in global public health, including within Indonesia. In addition to providing medications required for the treatment of diseases, the pharmaceutical industry contributes to enhancing the quality of life of the populace by introducing novel innovations in medical therapies. In tandem with the advancement of science and technology, the creation of effective and safe medications has become increasingly complex, demanding substantial resources. Consequently, to ensure that such innovations may continue to flourish and achieve market acceptance, adequate legal protection over scientific works within the pharmaceutical sector is imperative. One of the most pertinent forms of legal protection is the protection of patent rights as

regulated under Law Number 65 of 2024 concerning the Third Amendment to Law Number 13 of 2016 concerning Patents (Lidya Shery Muis, Rahmi Jened, Nurul Barizah, 2025). Patent rights fall within the context of intellectual property, copyrights, patents, trademarks, and other intellectual property rights. Hence, the significance of reinforcing legal protection over intellectual property in Indonesia is essential (Samariadi, 2016).

Patents may serve as a vital catalyst in realizing the sustainability of the pharmaceutical industry in Indonesia. For this purpose, it is essential for the government to continuously enhance the quality of the existing patent system, both in terms of administrative procedures, legal protection, and the supervision of patent implementation itself (Inayah Azzahra Arief, Sitti Fattimah Madussila, 2024). The government may also play a role in facilitating collaboration among pharmaceutical corporations, research institutions, and universities in generating new innovations. Throughout the term of patent protection, the manufacturer or patent holder of said medication is entitled to manufacture, distribute, economically exploit, and prohibit unauthorized third parties from manufacturing such medications (Kusnatul Ismi dan Desy Ismah Anggraini, 2025).

Patent rights possess an exceedingly crucial role in protecting innovation within the pharmaceutical industry in Indonesia, whilst simultaneously maintaining the sustainability of this sector. Through a robust and integrated patent system, Indonesia can foster research and development of medications relevant to societal needs, strengthen the local pharmaceutical industry, and enhance public access to affordable and quality medications. Inherent within patent rights are exclusive rights, which denote that such rights are conferred by the State upon an inventor for their invention within the field of technology (Karimatussholikhah Rujitoningtyas dan Gevan Naufal Wala, 2025). To that end, synergy is required among the government, industry actors, and society to foster an ecosystem that supports the growth of an innovative and sustainable pharmaceutical industry, rendering optimal benefits to public health. Medication represents an essential component in ensuring public health. The Government bears responsibility for the availability, equitable distribution, and affordability of public health supplies. Medications are divided into two categories, namely patent medications and generic medications. A patent medication is a novel drug discovered based on pharmaceutical industry research that is granted patent rights for its production and marketing after undergoing various clinical trial stages and the patent registration process at the Directorate General of Intellectual Property. A generic medication is a drug whose patent term has expired, thereby enabling its production by all pharmaceutical companies without the obligation to pay royalties (Johannes, 2025).

Therefore, patent rights function not merely as a legal instrument to protect innovation, but also as an economic incentive that encourages corporations to persistently invest in research and development to yield new life-saving medical products. The patent rights granted to the pharmaceutical industry for a novel drug discovered based on such pharmaceutical industry research confer the right to manufacture and market it. A patent is an exclusive right granted by the State to an inventor for their invention in the field of technology. Exclusive rights are rights solely reserved for the holder thereof, such that no other party may utilize said rights without the prior consent of the holder (I Komang Agus tri Wismantara, Ety Isworo, 2025).

The existence of a robust patent system aligned with international standards in Indonesia is vital to creating an environment conducive to the growth of the pharmaceutical industry. Indonesia has on several occasions faced urgent circumstances, one of which is the limitation of pharmaceutical products in efforts to eradicate disease outbreaks that may jeopardize public health requiring intensive intervention. Such was the case for Hepatitis and HIV/AIDS patients in Indonesia several years ago. The government issued a policy for the implementation of patents by the government through the enactment of Presidential Decisions. Law Number 83 of 2004 concerning the Implementation of Patents by the Government on Anti-Retroviral Drugs as amended by Presidential Decision Number 6 of 2007 concerning the Amendment to Presidential Decision Number 83 of 2004 concerning the Implementation of Patents by the Government on Anti-Retroviral Drugs and Presidential Regulation Number 76 of 2012 concerning

the Implementation of Patents by the Government on Antiviral and Antiretroviral Drugs (Endang Purwaningsih, 2020).

However, notwithstanding that patent rights serve as an important tool of protection, their implementation in Indonesia faces a number of challenges. A primary challenge lies in striking a balance between the protection of patent rights and the public need for affordable medications. On the other hand, an overly stringent patent granting process and long-term exclusive rights cause drug prices to become exorbitant. Consequently, it is imperative to formulate policies that can equilibrate patent protection with the public necessity to obtain affordable and easily accessible medications.

2. METHODS

The type of research utilized by the author is Normative Legal Research as the research method. This type of research is conducted by examining theories, concepts, and statutory regulations relevant to the issues under discussion (Muhaimin, 2020).

3. FINDINGS AND DISCUSSION

The necessity for a system that legally protects inventors in the technical field of industrial processes has driven the implementation of patent laws in Indonesia. By granting rights to the first-to-file or the first applicant, the patent-granting authority provides protection based on both national and international law (*The Paris Convention*). Patents are included within intellectual property rights that necessitate registration to secure legal protection. This differs from copyrights and trade secrets, which constitute intellectual property rights that do not require prior registration to obtain legal protection. All patent systems adopted by nations across the globe mandate patent registration so that an invention may be granted patent protection. This registration function is none other than a manifestation of efforts to balance the public interest in technological development with the private protection of the right to securely enjoy the fruits of an inventor's intellectual work. In consideration of the temporary monopoly rights conferred by a patent, the inventor or patent holder must disclose the secrets of their invention. In this manner, it is ensured that inventions are not practiced in secrecy and the knowledge regarding said invention will not be lost upon the demise of the inventor (Cantika Zhahra Paramitha dan Ahmad Faozan, 2025).

Article 2 of Law Number 13 of 2016 concerning the Scope of Patent Protection stipulates that there are two types of patents, namely Patents and Simple Patents, which are further specified under Article 3 and reference Article 2 letters (a) and (b). It is clarified that a patent under Article 2 letter a is granted for an invention that is novel, contains an inventive step, and is industrially applicable. Simple patents under Article 2 letter b are granted for the further development of a novel invention, or an existing product or process currently available in the industry. The subject of a patent dictates that an inventor is an individual who realizes an idea leading to activities that produce the invention, whether individually or collaboratively. Patents relating to the inventor or retaining the rights of said inventor are linked to the core of the patent. Where an invention is created collectively by several individuals, the inventors are jointly entitled to the rights over the invention (Andi Muhammad Reza Pahlevi Nugraha, 2022).

The term of a patent commences on the date of grant or from the date of filing. One of the reasons patents are granted is to demonstrate appreciation to inventors for their efforts and investments made to generate the invention. Therefore, the term of a patent is of paramount importance. During such time, the patent holder may exploit their rights by granting permissions or licenses to individuals or groups regulated by them, subject to their terms (Utama, 2012). Save for specific actions, objects, or methods, no other party is permitted to perform the same acts. They are precluded from doing so until the patent term has expired.

The ideal principle of patent protection corresponds to the protection of other intellectual property rights. However, it is intended to protect those who invent something so that their ideas or works are

not taken for granted by others, enabling them to enjoy the fruits thereof. This is the product of their labor, intellect, and financial expenditure incurred to acquire it. Pursuant to Article 109 of Law Number 65 of 2024, it has also been determined that the use of a patent by the government may be executed in the event of interests relating to defense and security or urgent public needs. This implementation is conducted on a limited basis for domestic requirements and is non-commercial in nature. Patent Regulations in Indonesia permit the regulation of patent objects that may be requested by the government for the use of inventions; some of the objects for which a patent may be requested by the government include pharmaceutical and/or biotechnological products that are expensive and/or required to combat diseases causing high mortality rates, including diseases causing significant disability, which constitute public health emergencies affecting the world (Afrizal Akbar Fairuzaidan dan Aang Asari, 2025).

Legal protection for Patents is obtained through a registration system, which in this instance employs the Constitutive System. Under the Constitutive System, Patent Rights are granted based on registration, namely a registration process involving an application by the inventor and examination by the Directorate General of Intellectual Property Rights (Hafsari, 2021). This system emphasizes the registration process spanning from the application step to the examination. This system is also known as the Examination System.

A patent application must satisfy the prescribed requirements: formal/administrative requirements and substantive requirements. This also triggers two levels of review: a formal/administrative review and a substantive review.

Formal requirements encompass completeness in administrative and physical domains, such as: the date, month, and year of the Patent application letter, the full name and nationality of the inventor, the complete address, the title of the invention, the claims contained within the invention, a written description of the invention, drawings, and an abstract of the invention. The initial examination regarding the completeness of formal requirements must be concluded prior to entering the substantive examination stage. Generally, the background of patent protection is to respect the intellectual creations of others, enhance the motivation of inventors, foster investment, boost the national economy, prevent unfair business competition, preserve natural rights, and protect reputation. A patent provides protection to the inventor ensuring that the invention shall not be utilized, distributed, sold, commercially manufactured, imported, or used without the consent of the current owner. This constitutes a form of monopoly granted by the State to the applicant in exchange for the disclosure of technical information. The patent recipient possesses the exclusive right to monitor the use of the patented invention for a duration of 20 years. To enforce this right, the court acts to prevent patent infringement. Should a third party successfully prove the invalidity of the patent, the court may declare the acquired patent invalid.

The exclusive right of a patent owner to exploit their invention as an enterprise in connection with the patent, either independently or by granting authorization or a licensing permit to others, encompasses making, selling, employing, supplying, using, or adopting or supplying patent-pending products (Adam Afin Maulana dan Suwarno Abadi, 2025). This right represents a right that can only be exercised by the patent recipient and is exclusive, meaning that other parties are prohibited from performing such acts without the consent of the patent recipient. Patent Protection Under Law Number 13 of 2016 in Article 22 and Article 23 elucidates the duration of patent protection itself, whereby a patent is granted for a term of 20 (twenty) years commencing from the Filing Date, the term as referred to in paragraph (1) cannot be extended, and the commencement and expiration dates of the Patent term are recorded and announced through electronic and/or non-electronic media. In Article 23: A simple patent is granted for a term of 10 (ten) years commencing from the Filing Date. The term as referred to in paragraph (1) cannot be extended, and the commencement and expiration dates of the simple Patent term are recorded and announced through electronic and/or non-electronic media.

The duration of patent protection is determined as follows. First, a patent is granted for 20 years from the date of filing, and this term cannot be extended. Furthermore, the commencement and

expiration dates of the patent term are recorded and announced. Third, a Simple Patent is granted for 10 years from the date of receipt, and said term cannot be extended.

A patent granted for each application may only apply to a single invention or a plurality of inventions constituting a single unified invention. Applications are submitted upon payment of a fee to the Directorate General of Intellectual Property. The application shall be submitted in writing to the Directorate General of Intellectual Property in Indonesia. A patent certificate serves as proof of patent rights. Said patent becomes effective on the date of issuance of the patent certificate and applies retroactively from the filing date (Lidya Shery Muis, Rahmi Jened, Nurul Barizah, 2025). The patent recipient is the inventor who becomes the patentee, a person who has acquired the rights from the patentee, or a person who has acquired the rights from the aforementioned person registered in the general patent register. If at the time of filing the patent application, the invention is not identical to or part of a prior invention, then the invention is deemed novel. The granting of patent rights is territorial, meaning it is binding only within specific jurisdictions.

Patents play an exceedingly important and strategic role in social, national, and economic development. A state holding a vital and strategic role in a patent right provides administrative protection so that the owner may utilize it for themselves and, based on a rights agreement, enjoy or derive economic benefits for others. Patent protection is granted after registration by the Secretariat of Intellectual Property of the Ministry of Law and Human Rights.

The pharmaceutical industry is a sector that holds a critical role in the global health arena, including in Indonesia. Beyond providing the medications required to treat illnesses, the pharmaceutical industry also contributes to the improvement of the public's quality of life by introducing new innovations in medical therapies. Parallel to the development of science and technology, the creation of effective and safe medications has become more complex and requires massive resources. Therefore, to ensure that these innovations can continue to evolve and be accepted by the market, adequate legal protection for scientific works in the pharmaceutical sector is highly required. One of the most relevant instruments of legal protection is patent rights. In the context of intellectual property, copyrights, patents, trademarks, and other intellectual property rights have become increasingly valuable assets in this digital era (AMINUDDIN KASIM, 2023). In line with this, the importance of strengthening legal protection for intellectual property in Indonesia becomes ever more apparent.

Patents play an essential role in protecting innovation within the pharmaceutical industry. The pharmaceutical industry requires intensive research and development, which necessitates a legal protection mechanism capable of incentivizing businesses and individuals to invest in new discoveries. Absent patent protection, pharmaceutical companies might hesitate to develop new products due to uncertainties regarding the ownership of innovation. Consequently, patents provide legal certainty for innovators to control the outcomes of their discoveries, preventing others from utilizing them without authorization and securing financial gains from these outcomes.

Patent rights within the pharmaceutical industry bear a crucial role in safeguarding innovation and providing incentives for the development of new drugs. However, this protection also exerts a significant impact on the accessibility of medications for the public, particularly in developing nations such as Indonesia. When a drug is patented, the patent holder possesses an exclusive right to manufacture, distribute, and sell said drug, which frequently results in higher pricing for the medication. For many individuals with low incomes, the exorbitant cost of medication becomes a formidable barrier to obtaining necessary medical treatment.

In Indonesia, numerous medications originating from multinational pharmaceutical corporations have been patented, causing their prices to often be unaffordable for the majority of the population. Article 20 of the Patent Law regulates a patent validity period of 20 years, granting exclusive rights to the patent holder to control the market during that timeframe. Consequently, newly marketed drugs command high prices and can only be sold by the patent holder or parties licensed by them. This results in such medications being more expensive than generic drugs that can be manufactured by other

companies. Patents, as a component of Industrial Property Rights, hold a significant role in the industrialization process of a nation. The granting of patents subsequently supports technological innovation and invention activities that must be protected.

A manifest impact of high drug prices is the restricted access of the public to essential medications, particularly for diseases requiring long-term treatment, such as diabetes, hypertension, or cancer. This induces inequality in healthcare services, as only a small fraction of the population can afford to purchase the medications necessary to maintain their health. In this regard, although patent rights function to protect innovation, their impact on drug accessibility leads to inequity in the distribution of medication within society. A manifest impact of high drug prices is the restricted access of the public to essential medications, particularly for diseases requiring long-term treatment, such as diabetes, hypertension, or cancer (Faridnan, Sulbadana, Zulkarnain, 2025). This induces inequality in healthcare services, as only a small fraction of the population can afford to purchase the medications necessary to maintain their health. In this regard, although patent rights function to protect innovation, their impact on drug accessibility leads to inequity in the distribution of medication within society.

A solution that can be implemented to mitigate the negative impacts of patent rights on drug accessibility is by accelerating the registration process for generic drugs. Generic drugs are copies of patented drugs after the expiration of such patents and are typically sold at substantially lower prices. By expediting the approval process for generic drugs, the government can assist in lowering drug prices in the market, thereby enhancing public access to required treatments. With increasing awareness of negative environmental impacts, industrial design has become a tool to promote a more eco-friendly lifestyle. Rapid economic growth and consumption often exert negative impacts on natural resources and yield increased waste. Pharmaceutical product patent holders are entitled to secure legal protection during the implementation of the patent by the government, which has been guaranteed under the prevailing laws and regulations. The existence of such legal protection can be deemed a concrete manifestation that the government's implementation of pharmaceutical product patents does not restrict or impede the interests of the patent holder regarding the fulfillment of the exclusive rights granted by the state during the patent protection term. Exclusive rights constitute proprietary rights possessing economic value (economic rights) as a reward for the sacrifice of time, effort, intellect, and costs incurred to produce an invention (Direktorat Jenderal Kekayaan Intelektual, 2019). Patent holders possess not only exclusive rights, but their patents executed by the government have also given rise to specific rights for the patent holder implied in Law Number 13 of 2016 and Presidential Regulation Number 77 of 2020.

Pursuant to Article 112 paragraph (2) of Law Number 13 of 2016 and Article 15 paragraph (2) of Presidential Regulation Number 77 of 2020, pharmaceutical product patent holders may continue to fully exercise their exclusive rights over their patents, namely executing their patents and prohibiting other parties without their consent from manufacturing, using, selling, importing, renting, handing over, or providing for sale or rent or handing over the patented pharmaceutical product.

One form of written agreement utilized in the assignment of patents is a license. A license denotes a form of right to perform an act or a series of actions granted by an authorized party in the form of a permit. Absent such permit, said act or action constitutes a prohibited, invalid act that amounts to an unlawful act (*perbuatan melawan hukum*).

The issue of generic HIV/AIDS medication, which to date is being actively pursued and has become a race among several nations. If it is ultimately discovered, the inventor can protect it through a Patent, which eventually yields exclusive rights. Such exclusive rights pose a concern for developing and underdeveloped countries, including Indonesia, because the medication can only be enjoyed by the inventor. This concern should be addressed proactively by Indonesia by competing in research to discover such generic drugs, rather than passively waiting to see who or which country will discover the vaccine. At the very least, Indonesia should participate in the effort using all available human resources and research institutions.

Another alternative that may be taken into consideration is that, theoretically, the aforementioned patent exclusivity does not mean it is unlimited; rather, patents can be transferred via various mechanisms, one of which is through compulsory licensing. A license, as a form of granting permission, can be exclusive or non-exclusive. Pursuant to Law Number 65 of 2024 concerning Patents (hereinafter referred to as the Patent Law) Article 81, it is stated that a compulsory license is a form of non-exclusive compulsory license.

Under the provisions of Article 7 of the TRIPs Agreement and taking into account Paragraph 4 of the Preamble of TRIPs, the balance between rights and obligations cannot be obtained through the diminution of the patent holder's rights without adding to the collective interest of the broader community. This means that the individual rights of a patent holder must not be reduced for the benefit of another individual; only social and collective interests can justify the imposition of a compulsory license. A compulsory license may be granted to two categories of applicants, namely the Government (or a Government agency or a third party authorized by the state) and other private third parties. The application of a compulsory license, whether by the government or a third party, cannot be granted arbitrarily but must be based on specific grounds, including: to prevent the abuse of patent holder rights resulting from the exercise of other exclusive rights; to mitigate the non-existence or insufficiency of the implementation of the patented invention; for the public interest, including the urgent needs of a country or other extreme situations and conditions, or public interests that are not for commercial use; to anticipate if the Patent Holder or Licensee implements the Patent in a manner and form that harms the public interest; to manufacture patented pharmaceutical products in Indonesia for the treatment of human diseases; for the import procurement of pharmaceutical products patented in Indonesia but not yet capable of being manufactured in Indonesia for the treatment of human diseases; or to export pharmaceutical products patented and manufactured in Indonesia for the treatment of human diseases based on requests from developing or underdeveloped countries.

The grounds as mentioned above can certainly serve as the basis for the urgency of implementing a compulsory license if it is indeed to be applied to the patent licensing of generic HIV/AIDS medication. Indonesia has a good opportunity either as a licensor or a licensee. First, Indonesia acts as a licensor if the inventor is an Indonesian individual/legal entity, subsequently exporting the invention to treat/prevent the spread of HIV/AIDS based on requests from developing or underdeveloped countries. Second, Indonesia acts as a licensee if the invention is discovered by an inventor from another country; in this case, the applicant for the patent license can basically be the government or a third party. However, to anticipate monopolies that might be carried out by third parties, in the author's view, the role of the government as an applicant is more paramount.

State intervention in circumstances such as the present is non-negotiable to realize state objectives, particularly as an applicant for a compulsory license if Indonesia acts as a licensee. This is aligned with Article 8 of the TRIPs Agreement, which states that member states may adopt or amend their laws and regulations to establish the protection measures necessary for public health (Samariadi, 2016). Furthermore, compulsory patent licensing in the pharmaceutical field also provides easier access to medications originating from developed countries and renders the prices of such medications more affordable.

The implementation of compulsory patent licensing is of critical urgency, which is predicated upon the conflicts of interest therein, particularly political and economic interests. This consequently results in disharmony in the administration of public policy in general and compulsory patent licensing in particular, which will sacrifice the interests of the broader public.

4. CONCLUSION

Legal protection of patent rights provides legal certainty as well as vital economic incentives for the pharmaceutical industry to conduct research and development. Patent rights within the pharmaceutical industry play an essential role in safeguarding research results and innovation, yet they impact the accessibility of medications for the public. High drug prices resulting from the exclusive

rights of patent holders present a major obstacle, particularly for low-income communities. The government possesses the authority to intervene through mechanisms such as compulsory licensing or government patent exploitation under specific health conditions to ensure that the availability of medication remains guaranteed and easily accessible to the public.

A balance is required between patent protection and access to medication, namely by accelerating the production and distribution of generic drugs after the expiration of the patent term, as well as providing incentives to local pharmaceutical companies to innovate. The government needs to reinforce regulations and intervention policies, such as mechanisms for state patent exploitation, to ensure that public needs for essential medications can still be met despite being within the patent protection period. Enhanced collaboration among the government, higher education institutions, and the pharmaceutical industry in drug research and development is necessary to create pharmaceutical innovations relevant to public needs while simultaneously strengthening national competitiveness within the scope of Pharmaceuticals.

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