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Patent protection legal facility for access and availability of pharmaceutical products

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Abstract

Patent protection in the pharmaceutical sector plays a dual role: it provides incentives for innovation while simultaneously raising barriers to affordable access to essential medicines. This tension becomes particularly urgent in developing countries such as Indonesia, where high drug prices, unequal distribution, and limited insurance coverage constrain public health rights. This study aims to analyze the legal facilities available under international and national frameworks to balance patent protection with the right to health, focusing on compulsory licensing, government use of patents, parallel imports, and the bolar provision. The research adopts normative legal methods using statue, conceptual, and comparative approaches, with reference to the TRIPs Agreement, Indonesian Patent Law No. 13 of 2016, and relevant case studies. The findings demonstrate that while Indonesia has utilized TRIPs flexibilities such as government use of patents for HIV/AIDS and Covid-19 medicines, the implementation remains fragmented and hampered by weak regulation of parallel imports and data exclusivity. The comparative analysis highlights how other jurisdictions provide clearer safeguards to ensure accessibility while maintaining incentives for innovation. This study concludes that reform is required in Indonesian patent law to strengthen the balance between innovation incentives and public health needs. Clearer regulatory guidelines, transparent remuneration schemes, and stronger distribution mechanisms are essential to guarantee drug availability and affordability, especially during health crises.

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Introduction

Access to affordable medicines is a fundamental component of the right to health, yet it remains a persistent challenge in many developing countries, including Indonesia. The pharmaceutical industry is heavily driven by patents, which grant exclusive rights to inventors as incentives for costly and high-risk research and development. However,

while patents stimulate innovation, they often result in high drug prices and limited availability, creating tension between intellectual property protection and public health needs. A study conducted by the Indonesian Ministry of Foreign Affairs highlighted that patent monopolies contribute significantly to restricted access, particularly for populations in low- and middle-income countries. This problem is further compounded by the circulation of counterfeit medicines, the prevalence of expired drugs, and the risks posed by uncontrolled online sales.

The urgency of this issue became even more evident during the Covid-19 pandemic, when shortages of essential medicines, vitamins, and antibiotics underscored the vulnerability of health systems dependent on patented pharmaceutical products. Indonesia's experience demonstrated that ensuring drug availability is not only a matter of public health policy but also one of legal design, where patent law must accommodate mechanisms that balance innovation incentives with accessibility. The Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement recognizes this tension and provides flexibilities such as compulsory licensing, government use of patents, parallel imports, and the bolar provision. These mechanisms are intended to safeguard public access to medicines while maintaining respect for intellectual property rights.

Existing scholarship has extensively discussed the global implications of TRIPs flexibilities and their role in promoting access to medicines. However, studies that specifically examine the Indonesian context remain limited, particularly in assessing the effectiveness of legal facilities provided under national law in securing access to essential medicines. This creates a research gap in understanding how Indonesia utilizes TRIPs flexibilities in practice, what challenges hinder their optimal implementation, and how these mechanisms can be strengthened to support the right to health.

This paper therefore seeks to analyze the legal facilities for patent protection in the pharmaceutical sector within Indonesia, focusing on the mechanisms of compulsory licensing, government use of patents, parallel imports, and the bolar provision. By employing normative legal research with legislative, conceptual, and comparative approaches, this study aims to evaluate the adequacy of Indonesia's regulatory framework and to identify potential reforms necessary to ensure that patent protection does not undermine, but rather reinforces, the constitutional mandate to guarantee access to medicines and promote public welfare.

Method

This kind of research is called normative legal research. The methods used in this study include the legislative approach, the conceptual approach, and the comparative approach. The legislative approach involves looking at laws and rules related to patents, health, and medicines. The conceptual approach looks at legal ideas that experts have shared in different writings about patents, health rights, and access to medicines. The comparative approach compares how the law works in Indonesia with how it works in

another country that has already made these laws, especially regarding mandatory licenses, how the government handles patents, parallel imports, and bolar provisions.

Results and Discussion

Legal facility for pharmaceutical product patent protection

In the pharmaceutical sector, people in the health industry say that private companies are really needed. They mentioned that the pharmaceutical industry spends more money on research and development compared to other industries. Even though creating new drugs is very costly, it's easier for others to copy existing drugs.[1] The patent system lets companies set higher prices for drugs than the cost of making and selling them, which is supposed to cover the money spent on developing the drug. Once the patent protection ends, other companies can make cheaper copies of the drug, leading to lower prices.[2] Even though the pharmaceutical industry wants strong patent protection, some countries put limits on drug patents for the public good. Patents on drugs are now common in the industry and have led to more patents for new medicines. However, there is debate about whether patent protection for drugs and drug research for certain diseases in poorer countries is helpful, because patents don't always lead to more development for diseases that mainly affect the poor. This creates a conflict between the pharmaceutical industry's goal of getting a return on its investment and the government's goal of keeping healthcare costs low.[3]

Accessibility in health care means making sure that everyone, especially those who need it, can get medicine at a price they can afford. However, when there are rewards for creating new medicines, it often leads to higher drug prices. This makes it hard for poor people to get the medicines they need. In many developing countries, people don't have health insurance and often pay for their own medicine.[4] The cost of medicine is a big problem for access. Even though generic drugs are cheaper, they may still be too expensive for people living in poverty. To make sure everyone can get the medicine they need, governments may have to offer help through subsidies or control drug prices.

The uneven spread of medicines leads to limited access to them. One reason for this is that for many types of drugs, pharmaceutical wholesalers have to provide storage facilities with refrigeration to keep the medicines safe and also need pharmacists to handle the distribution. These limited resources make it hard for wholesalers to send medicines to remote or hard-to-reach areas, which makes it difficult for people to get the medicines and causes prices to go up.[5]

[1] (Muis et al., 2023)
[2] (Muis et al., 2023)
[3] (Muis et al., 2023)
[4] (Muis et al., 2023)
[5] (Muis et al., 2023)

Not knowing how to take action to reduce this gap leads to mistakes in how drugs are distributed. In Indonesia, drug distribution should be seen as part of improving public welfare, not just as a business activity. This is because every part of the drug distribution system, from the pharmaceutical companies to the people who use the drugs, needs protection. [6] According to the TRIPs Agreement, the government can make some exceptions to patent rights, but only if certain conditions are met. TRIPs also allows for different ways to handle drug patents, such as mandatory licensing, government-led patent implementation, importing drugs from other countries, and early access for research and development purposes.[7]

Mandatory license

The Paris Convention provides member states with the opportunity to regulate mandatory licensing to prevent infringements arising from the exercise of exclusive rights to patents. Article 5A Paragraph (2) to Article 5A Paragraph (5) of the Paris Convention provides freedom for member countries to set the period for the application of a compulsory license if due to non-execution of a patent. Compulsory licenses are regulated in Article 31 TRIPs, in that article the use of a patent by another party without a permit is permissible if the use of the patent meets various requirements, starting from the initial application process to implement the patent to the provision of adequate compensation (royalty) to the patent holder.[8]

The decision of the 2003 TRIPs General Council contains provisions for the abolition of the provisions of Article 31 letters (f) and (h) of TRIPs. This is confirmed in Article 31 bis, which says that the obligations of an exporting Member under Article 31(f) do not apply when it gives a compulsory license for the production of a pharmaceutical product and its export to an eligible importing country. Also, Article 31 bis, number 2, states that:

Where a compulsory license is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory license is granted for the same product in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

Through changes to this article, the General Council of TRIPs broadens the use of mandatory licenses. Before, these licenses only allowed drugs to be made and sold within a country. Now, they can also be exported or imported. After the TRIPs General Council made this decision, Article 31 bis explains how countries can use mandatory

[6] (Aktieva Tri Tjitrawati, 2013)
[7] (Correa, n.d.)h. 13
[8] (Muis et al., 2023)

licenses to import or export drugs. It also sets rules about paying patent holders for using their patents to make these drugs.[9]

According to Rajeev Dhavan, Lindsay Harris and Gopal Jain, IPR divides member countries into producing and non-producing countries. Implicitly the goal is to seize foreign import monopolies for producing countries.[10] Therefore, the convention allows foreigners to obtain patent monopolies without the obligation to produce the patented goods or even to ensure its supply in the patenting country. Another debate that started to attract public attention when Brazil ran against the United States in the WTO.[11] The Brazilian government has chosen to give local drug makers permission to produce generic medicines that are crucial for the country. The idea of giving these licenses is clearly explained in Article 31 of TRIPs, but using them is a topic of debate. For instance, there's a question about how to handle these licenses when the main reason for using them is the high cost of medicines, like those for HIV and AIDS. According to TRIPs, there are special situations where it is permissible to use a mandatory license to circumvent strict patent restrictions.[12]

Execution of patents by the government

Provisions that allow the government to use patents are a way for the government to be protected from patent claims when it needs to meet important national needs for the public good, especially in areas like national security, food, health, or other essential parts of the economy. The rules about how the government can use patents are explained in Article 31 of the TRIPs agreement. This rule lets WTO member countries use a patent without asking the patent owner's permission, but only if it's for the public interest. The patent owner can still get royalties, but they can't stop the government from making generic medicines or let others make or bring in those medicines.

Patents are allowed to be implemented by the Government itself as regulated in the Patent Law No. 13/2016, also regulated in Presidential Regulation Number 77 of 2020 concerning Procedures for the Implementation of Patents by the Government. As for the consideration of patent implementation by the government, it is regulated in Article 109 Paragraph (1) of Law No. 13/2016 and also regulated in Article 2 of Presidential Decree No. 7/2020, namely:[13]

1. Relating to national defense and security.
2. The need is urgent for the benefit of society. For example, in the health sector, such as medicines that are still protected by patents in Indonesia, which are needed to deal with diseases that are widely infected.

[9] (Shery Muis, 2024)
[10] (Rajeev Dhavan, n.d.)
[11] (A Ardagh, 2003)
[12] (Russo, 2015)
[13] (Shery Muis, 2024)

The implementation of a patent by the government is stipulated by Presidential Regulation, limited to meeting domestic needs, non-commercial in nature, within a certain period of time and can be extended with the consideration of the relevant Minister.[14]

Article 5 of the Presidential Decree says that if the government can't carry out a patent by itself, as mentioned in the decree, it can choose another company to do it. But this company must meet certain conditions. First, they must have the necessary facilities and be able to apply for patents. Second, they can't pass the responsibility of implementing the patent to someone else. Third, they must have good ways of making products, distributing them, and keeping things under control, following the rules set by laws and regulations.[15]

In Article 13 of the Presidential Decree, the government can use patents for certain products when there is a very urgent need that benefits the community. These include:

1. Pharmaceuticals and/or biotech products that are costly and/or needed to treat diseases that can cause many deaths quickly, lead to serious disabilities, or create a major public health crisis that affects the world;
2. Chemical and/or biotech products used in agriculture that are important for ensuring food supply;
3. Veterinary medicines used to handle widespread pests and/or animal diseases; and/or
4. Processes and/or products used to manage natural disasters and/or environmental disasters.

The government must give fair payment to the owners of patents. This is stated in Article 115, Paragraphs (1) and (2) of Law 13/2016. If the government gives the patent rights to someone else, then Article 31, Paragraph (3) of Presidential Decree 77/2020, which talks about how the government uses patents, says:

If the government uses the patent through a third party they have chosen, then that third party must give the payment as mentioned in Paragraph (1).

If the patent owner disagrees with the amount of money the government offers, they can take the case to a commercial court.

In that case, the cost of using the patent by the government will be paid from the state's budget. Indonesia is one of the countries that takes advantage of the flexibility of patent application by the government. The high number of HIV/AIDS sufferers requires Indonesia to meet the need for essential medicines, but the high price of Antiviral and Antiretroviral drugs results in limitations in access and availability. To reduce the number

[14] (Shery Muis, 2024)
[15] (Lidya Shery Muis, 2023)

of people living with HIV/AIDS, the government uses the flexibility of TRIPs in the form of implementing patents by the government to maintain the availability of Antiviral and Antiretroviral drugs. The government has used this flexibility 3 (three) times. First, through Presidential Decree No. 83/2004 for *Navirapin* and *Lamivudin*. Second, through Presidential Decree No. 6/2007 for *Navirapin, Lamivudin,* and *Efavirenz.* Finally, through Presidential Decree No. 76/2012 for *Efavirenz, Abacavir, Didanosine*, the combination of the active substances *Tenofovir* and *Emtrisitabin* and the combination of the active substances *Tenofiovir*, *Emtrisitabin* and *Efavirenz* whose patent protection period ends on November 3, 2024. Companies holding patents are given a remuneration of 0.5% and are not disputed by the patent holder. During the Covid-19 pandemic, medicine is of course one of the most urgent needs for the benefit of society. In practice, not all parties have access to the drugs needed. This can happen because the demand for drugs is very high, but there isn't enough supply of raw materials or the ability to make them, which leads to higher prices for these drugs. For this reason, the government needs to create policies that help people get the medicines they need. One such policy is the government implementing patents, which can help improve access to drugs during the Covid-19 pandemic.[16]

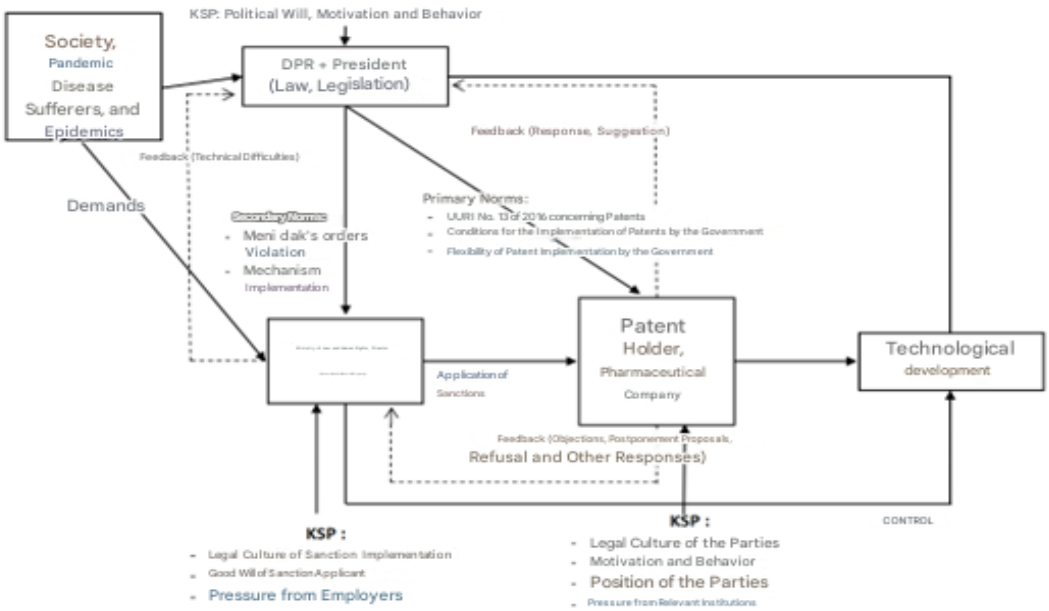

Figure 1. The Works of Law by William J.Chambliss and Robert B. Seidmen Compiled from various sources.[17]

The implementation of patents by the government is determined by the legal relationship between the Government, the Ministry of Law and Human Rights, Directorate General of Intellectual Property, Food and Drug Monitoring Agency, patent holders, pharmaceutical companies, the public and technological developments. This

[16] (Muis et al., 2023)
[17] Compiled from various sources.

relationship can be described using the theory of the working of law put forward by William J. Chambliss and Robert B. Seidmen.

According to William and Robert, the legal process is determined by four main components, namely:[18]

1. law-making institutions, namely the DPR and the president;
2. law enforcement bureaucracy, namely the Ministry of Law and Human Rights, the Director General of Intellectual Property Rights, Food and Drug Monitoring Agency;
3. the role holders namely patent holders and pharmaceutical companies;
4. the influence of personal strength, namely the community and pandemic sufferers.

The first three parts are the groups that make laws, the groups that carry out the laws, and the people who work in the legal system. Personal influence and social power are not part of the legal system.

The Government of the Republic of Indonesia applies the patent rights to the drug *Favipiravir* to guarantee the availability of the drug so that it can be distributed to people affected by Covid-19. *Favipiravir* is one of the drugs that might help reduce Covid-19 in Indonesia. Expensive drug prices, the availability of ingredients or drug production that is not in proportion to the need for drugs are the reasons the government has issued steps to apply for patents on *Favipiravir* which are expected to be able to handle drug access in the midst of a pandemic.[19]

Directorate General of Intellectual Property cooperates with factories owned by Indonesian pharmaceutical companies. PT. Kimia Farma Plant Banjaran to produce *Favipirafir* in large quantities so that the drug can be widely distributed in every health facility, and hopes to obtain a patent from the Government of Indonesia. *Favipiravir* is one of the mildest of the several alternative Covid-19 drugs. The implementation of this patent by the government is an effort to ensure the availability of the drug *Favipiravir* as a Covid-19 drug at an affordable price.[20]

Favipiravir compound registered in Indonesia belonging to the Japanese pharmaceutical company, Toyama Chemical Co., Ltd. and 1 (one) Patent owned by a British pharmaceutical company, *Glaxosmithkline*. The selection of the *Favipiravir* drug patent was based on a proposal from the Minister of Health to the Law and Human Rights through letter Number HK.08.01/Menkes/811/2020. The letter states that in order to ensure the availability of *Favipiravir* and *Remdesivir* drugs as therapy in handling Covid-19 according to the Covid-19 Management Guidelines from the Indonesian Pulmonary

[18] ("Hukum dan Alih Teknologi (Sebuah Pergulatan Sosiologis)," 2013)h. 21
[19] (*Agenda KI*, 2023)
[20] (*Agenda KI*, 2023)

Doctors Association (PDPI) and 4 (four) other specialist medical associations, it is necessary to immediately apply for patents by government.[21]

Food and Drug Monitoring Agency issues an *Emergency Use Authorization* (EUA) permit[22] for the use of *Favipiravir* for the Pharmaceutical Industry PT. Beta Pharmacon (Dexa Group) with the trademark Avigan and to PT. Kimia Farma Tbk. which is currently producing the generic product *Favipiravir* in Indonesia. Permission to use *Remdesivir* has been granted to the Pharmaceutical Industry PT. Amarox Pharma Global, PT. Indofarma, and PT. Dexa Medica.[23] The President has also allowed the government to use the patents for Remdesivir under Presidential Decree No. 100/2021 and for Favipiravir under Presidential Decree No. 101/2021. The patent use will last for 3 years from when the decree starts to take effect. If the pandemic is still going on after this time, the government will keep using the patents until the government officially says the Covid-19 pandemic is over. According to the Minister of Health's decree number HK.01.07/MENKES/4826/2021 about the highest retail price for drugs during the pandemic, Favipiravir 200 mg tablets were sold at IDR 22,500 each and Remdesivir 100 mg injections at IDR 510,000 per vial.[24]

Parallel import

Parallel imports are original products that are imported without permission from the patent holder and are marketed in other countries. Parallel imports allow importers to sell products at a lower price than the price set by the patent holder. Parallel imports, sometimes called "gray market" imports, are products made under the protection of intellectual property rights like patents, copyrights, and trademarks. These items are sold in one market and then brought into another market without the permission of the rights holder in that second market. For example, a company might buy certain medicines in Spain and then import them into Sweden or Germany without getting approval from the local distributor who has the official patent rights.[25]

In the Indonesian Patent Law, parallel imports are not allowed because the patent holder is given exclusive rights by the government under Article 19 of Law No. 13/2016. This exclusive right lasts for 20 years, and during this time, the patent holder can use the patent and stop others from doing certain things without permission. If the patent is for a product, the patent holder has the right to make, use, sell, import, rent, deliver, or make the product available for sale or rent. If the patent is for a process, the patent holder can use the process to make goods or do any of the things mentioned above for a product patent.

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[21] (*Agenda KI*, 2023)

[22] EUA is an approval for the use of drugs or vaccines during a public health emergency, in this case the Covid-19 pandemic.

[23] (*Agenda KI*, 2023)

[24] (Lidya Shery Muis, 2023)

[25] (Maskus, n.d.-b)

Exceptions are possible as long as the parallel import is carried out in a procedure that is not against the law and takes into account the legitimate interests of the patent holder. Parallel imports are important for Indonesia because of the level of economic development and global competition.

Article 167a of Law No.13/2016 states that "a pharmaceutical product that is protected by a patent in Indonesia and the pharmaceutical product in question has been legally marketed in a country provided that the pharmaceutical product is in accordance with the provisions of laws and regulations". The reason for not allowing the import of pharmaceutical products is to ensure fair pricing and provide justice for medicines that are essential for human health. According to Article 167a of Law No.13/2016, the exception for parallel imports of medicines is meant to ensure fair prices and provide justice for important medicines that people need. This rule allows for parallel imports if the cost of medicines in Indonesia is much higher than the prices that are officially allowed in the market.

In patent protection, there is a rule that limits how much control the patent holder has over their product, called the principle of exhaustion. This principle has three types: international, national, and regional. International exhaustion means that once the product is sold anywhere in the world, the patent holder's rights end, and bringing in similar products from other places is allowed. National exhaustion means the patent rights end when the product is first sold within a specific country, but the patent owner can stop products brought in from other countries. Regional exhaustion means the patent rights end when the product is first sold in a group of countries, allowing products to be sold between those countries, but not if they are brought in from outside the region.[26]

Parallel imports do not conflict with the exhaustion principle because of the exhaustion principle stated that the patent holder's rights to his patented product were deemed to have ended after the first sale was carried out and circulated in the international market. This means that the exclusive rights enjoyed by the patent holder are only up to the sale of the product. Patent holders only enjoy their exclusive rights to the extent of their patents until the first sale. [27]After that the exclusive right expires (exhaust) and has no right to prevent or hinder further sales (re-sale). Thus, athe patent holder cannot control the distribution channel taken by the consumer, unless otherwise specified in the license agreement. Parallel imports in the Indonesian patent law need to be regulated more clearly and strictly because the guidelines related to permitted activities, including the issue of parallel import licensing, are still not very detailed in the regulations in the field of patents.[28]

[26] (Maskus, n.d.-a)
[27] (Yuswanto, 2017)h. 109
[28] (Yuswanto, 2017)h. 110

The implementation of parallel imports reaps pros and cons between countries. Proponents of international patents prohibit parallel imports of new drugs on the grounds that such trade is permitted widely to reduce profits and research-intensive pharmaceuticals, resulting in a decline in new drug innovation. Parallel imports can make it hard for health authorities in different countries to follow their own price controls and rules, which may vary from one country to another. Public health officials in many places believe that allowing parallel imports is important because it lets them purchase medicines from suppliers at very low costs. However, this might also push suppliers to lower their prices. It is clear that policymakers, especially in developing countries, will focus more on making medicines affordable rather than encouraging research and development abroad.[29]

Such an agreement may be difficult to reach due to differing views on the benefits of parallel imports. Article 6 TRIPs only states that:

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of Intellectual Property Rights.

This article suggests that there are no restrictions or limits on using parallel imports under the National Treatment and Most Favored Nation principles. There is some debate about how this should be understood, but generally, Article 6 allows each country to decide its own rules about parallel trading. This freedom is important because it helps many developing countries get exemptions under the TRIPs agreement. Delegates from developing countries view parallel imports as a way to address worries about high drug prices caused by patent laws in the agreement.[30]

Restrictions on bringing in the same medicines from different countries create a problem for trade that isn't tied to tariffs and go against the basic rules of the World Trade Organization. People who support these restrictions often say that national rules need to be strict when it comes to exporting and importing medicines, especially because prices can vary a lot around the world.[31] There are two main things that need to be made clear. *First*, people who oppose parallel imports claim it leads to fraud, selling fake goods, and pirated products. But this argument isn't really about the effects of parallel imports. Fraud happens when lower quality medicines are sold as the real, higher quality ones. Selling fake or copied goods is different from parallel imports, and in both cases, customs officials can stop these illegal activities without stopping real parallel imports. *Second*, a ban on parallel imports doesn't stop the import of generic drugs or fake drugs from other countries.

[29] (Yuswanto, 2017)
[30] (Maskus, 2004)
[31] (Maskus, n.d.-b)

This is because the original medicine isn't patented there. If selling the medicine in your own country breaks the patent, then parallel imports might not be allowed for that reason.[32] Some countries prohibit the parallel import of drugs because their patent laws grant strict import rights to holders of legal licenses. Hong Kong and Singapore prefer open parallel trading regimes due to their nature as entry points for trade centres. India follows an international system where trademarked goods and patented products are allowed to be used after a certain period. Some developing countries, like Argentina, Thailand, and South Africa, have laws that let people import medicines from other countries without needing to get approval from the local country.[33] Drugs imported in parallel must meet the following requirements:[34]

1. They must have been allowed to be sold in the country where they were made;
2. They need to be similar enough to the medicine that is officially approved in the country where they are going.

Two medicines are considered similar if they have the same formula, the same active ingredients, and are used for the same medical purpose. As long as public health is taken care of, these imported medicines can be sold even if the original approved medicine is no longer available in the market.[35]

The benefits of parallel imports are:[36]

1. help lower the cost of branded medicines right away;
2. can work along with price control efforts. This helps healthcare providers have more power to talk with the original drug makers, which can lead to lower prices.

The drawbacks of parallel imports are:[37]

1. If the original drug makers set prices based on market conditions, bringing in parallel imports can make medicines more expensive in the countries they are sent to because there are fewer medicines available. In such cases, the original producers might stop supplying that market;
2. The cost of shipping and repackaging medicines during parallel trade can take away much of the price savings;
3. Parallel import companies don’t spend money on research and development or advertising. They usually use the marketing costs from the original manufacturer and its partners, which might make them less interested in supplying certain markets or products;

[32] (Rozek & Berkowitz, 2005)
[33] (Rozek & Berkowitz, 2005)
[34] (Rozek & Berkowitz, 2005)
[35] (Rozek & Berkowitz, 2005)
[36] (Rozek & Berkowitz, 2005)
[37] (Rozek & Berkowitz, 2005)

4. Parallel imports reduce the profits of the original drug makers. This could affect their research and development plans, as these are sensitive to lower profits, and might slow down the development of new medicines worldwide.

Parallel imports happen when there are big price differences between countries, and the cost of moving and selling medicines across borders is not too high. If allowed, they might help make the prices of the same medicines similar in different markets. However, differences might still exist because of shipping costs, taxes, regulations, and other fees. The main reason for parallel imports is when drug makers set different prices in various markets. They do this to make the most profit by charging more in markets where people are less sensitive to price changes. Larger markets with less price-sensitive buyers tend to have higher prices, while smaller markets with more price-sensitive buyers accept the product at a lower cost.[38]

Bolar provision

A bolar exemption, also called a research exemption, is now commonly known as a bolar provision. It is an exception to the rights given by a patent, especially for drugs. This rule says that even though the patent holder does research and tests to get approval from regulatory bodies, like the FDA in the U.S., it's not a violation of the patent for a limited time before the patent ends. This allows generic drug makers to start making their products before the patent is up. In the U.S., this exception is also called the Hatch-Waxman Act. In 2005, the U.S. Supreme Court looked at the case of Hatch-Waxman v. Merck. The Court said that using a substance for reasonable purposes to provide information to the government for drug-related laws isn't a crime.[39] In Indonesia, the bolar provision is covered in Article 167(b) of Law No. 13/2016, and also in Article 13 of the Minister of Health Regulation Number 1010/MENKES/PER/XI/2008 about drug registration. The bolar provision helps ensure that people have access to medicines. It's a permission from the government that lets generic drug makers use patented inventions to develop and provide information required by law, without needing the patent owner's permission, before the patent's protection ends. Once the patent expires, the generic drug makers can then put their versions on the market.[40]

Article 167, letter b, of the Patent Law No. 13/2016 says that in Indonesia, it's allowed to make patent-protected medicines for five years before the patent ends. This is done to prepare for licensing and then selling the medicine after the patent is no longer valid. The explanation of Article 167, letter b, says that this rule, called bolar provisions, helps make sure that other companies can get medicines available once the patent is over. It also helps keep the cost of medicines reasonable. The licensing process is about getting permission to produce and sell a medicine from the right government body. So, before

[38] (Subramanian, 2014)
[39] (Weschler, n.d.)
[40] (Shery Muis, 2024)

the patent ends, other companies can start researching and getting permits to make the medicine from BPOM, while they wait for the patent to expire. Once the patent is up, they can then sell the generic version of the medicine.[41]

The introduction of bolar provisions means that the inventor or their company gets more protection than what is required by the TRIPs agreement. This is called TRIPs-Plus. One key example of this extra protection is data exclusivity. Data exclusivity means that the clinical trial data needed to show a medicine is safe and works well must be kept private. This stops generic drug makers from using that data in their own applications. This is a type of protection that comes from patents.[42]

Pharmaceutical companies keep the test data private because the R&D process is very expensive and they feel it is unfair to let other companies have access to the data for free. Do not increase drug prices, it will prevent prices from falling because the price of generic drugs is not necessarily cheaper than the price of the imitated drugs because the R&D costs for imitating the active substance of the drug are not small. Drugs remain expensive even though the patent has expired. This is contrary to the goal of implementing bolar provision, which is to provide cheap and affordable generic versions of essential drugs as soon as the patent expires so that people, especially the poor, can access drugs that are urgently needed to save lives, for example anti-HIV/AIDS & anti-malarial drugs.

One important problem here is the issue of data exclusivity for new drug companies. From an economic angle, industries where research and development are costly and risky need more time to protect their inventions, compared to industries where innovation is quicker and less expensive. Keeping pharmaceutical data exclusive can stop public knowledge from spreading quickly, which is a trade-off for getting patents. Data exclusivity is like a long-term patent that can stop governments from getting benefits from grants, because even if a patent is given, data monopolies can stop the sale of cheaper generic drugs.[43]

Another problem with data exclusivity is related to medical ethics and research. It is considered unethical, according to the Helsinki Declaration, to repeat clinical trials on people[44]. Similar problems have happened in areas like agriculture and cosmetics, where test data is protected. Because of this, some countries have suggested sharing costs for test data protection.[45]

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[41](Muis & Hamid, 2024)

[42] (Mossinghoff, 1999)

[43] (Thomas Faunce; Tim Vines; Helen Gibbons, n.d.)

[44] *Helsinki The Declaration* is a set of ethical principles regarding human testing developed for the media community by *the Medical Association*. This Declaration is generally considered to be the underlying document for the ethics of human research.

[45] (Thomas Faunce; Tim Vines; Helen Gibbons, n.d.)

Data exclusivity and patents are two key rights in the creation and management of intellectual property rights (IPR), especially in the pharmaceutical sector. These rights are different kinds of protection. The protection of one does not depend on or connect with the other in any way. The time periods for these protections do not conflict with the rules set out in the TRIPs Agreement. Each type of IPR has its own unique features, which are clearly shown in the structure of the TRIPs Agreement. The Agreement addresses each right separately and in parallel in Part II, covering the standards for availability, coverage, and how these rights can be used.[46]

Article 39.3 of TRIPs deals with the protection of confidential information and shows the need for governments to protect data registration rights.

While WTO members are required to offer data rights protection that matches their commitments under Article 39.3, many countries have not done this properly. Some countries do not protect proprietary registration data at all. Others offer some protection, but not enough to meet the requirements of Article 39.3 TRIPs.[47]

Clinical and pre-clinical trial data that companies send to regulatory agencies was the main topic of discussion regarding data exclusivity. Bio-equivalence data, for example, only shows that a generic drug works the same as the original medicine, meaning it is safe and effective. So, generic companies and the regulators kind of depend on the data provided by the original drug makers. The original companies say they spent a lot of money on these trials, so they should be allowed a certain time period where regulators can't use their data to approve generic versions of the same medicine. This means that as long as this exclusivity period is in place, generic makers have to do their own testing to prove the safety and effectiveness of their drugs. This would require them to repeat clinical trials and other tests, which could take a long time. Many generic companies might not be able to handle the cost of doing this just for commercial reasons, so they might have to delay launching their products until the exclusivity period is over. This slows down the introduction of generic drugs, which in turn delays competition and lowers drug prices.[48]

The period of data exclusivity is usually shorter than the length of a patent. Data exclusivity can stop generic drugs from being approved even if there are no patents on them. This can happen when a drug isn't considered new enough to get a patent, or in countries that don't have patent laws, or if no patent was granted for the drug. This situation might occur in developing countries where WTO members are not required to grant patents for medicines.[49]

[46] (South-East Asia World Health Organization Regional Office, 2017)
[47] (South-East Asia World Health Organization Regional Office, 2017)
[48] (Correa Carlos M., 2004)
[49] (Correa Carlos M., 2004)

Drug companies should work with governments and key stakeholders to increase transparency and accountability to ensure that the public, as well as health professionals, have a meaningful opportunity to participate in the negotiation process and seek to challenge the provisions that reduce the protection provided by the flexibility of TRIPs in trade agreements bilateral and multilateral.[50]

Conclusion

The protection of pharmaceutical patents is intended to reward innovation and sustain investment in research and development. However, in practice, it often creates significant barriers to the accessibility and affordability of essential medicines, particularly in developing countries such as Indonesia. This study shows that while Indonesia has adopted various TRIPs flexibilities—including compulsory licensing, government use of patents, parallel imports, and the bolar provision—these mechanisms are not yet fully optimized in ensuring equitable access to medicines.

The Indonesian experience in granting government use licenses for antiretroviral and Covid-19 drugs demonstrates that patent flexibility can effectively address urgent public health needs. Nevertheless, challenges remain, including regulatory inconsistencies, limited legal certainty in parallel importation, and the unresolved issue of data exclusivity that may hinder the rapid entry of generic drugs into the market.

To strengthen the balance between patent protection and the right to health, Indonesia must reform its patent regulatory framework by clarifying procedures, enhancing coordination among government institutions, and establishing transparent and fair remuneration mechanisms for patent holders. In addition, the state must improve drug distribution systems to prevent disparities in access across regions. By doing so, Indonesia can ensure that patent law not only protects innovation but also fulfills the constitutional mandate to safeguard public health and guarantee the availability of essential medicines for all citizens.

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