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Urgency of bolar provision regulation on patented drugs for access and availability of generic drugs for public health

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Abstract

Limited availability of medicines is a serious problem in fulfilling the public's right to health. The monopoly of patented medicines by patent-holding pharmaceutical companies has resulted in generic pharmaceutical companies not being able to access information about patented medicines even though the patent has expired. This certainly hinders the immediate circulation of generic versions after the patent expires. Generic medicines are important because they are easier to access, more widely available, and cheaper than patented versions of medicines. To overcome this problem, a legal means called bolar provision is regulated. Bolar provision is a permit granted by the state to generic pharmaceutical companies to use patented inventions to develop and deliver drug information without the patent owner's permission 5 (five) years before the patent protection period ends. Generic pharmaceutical companies can then market generic versions after the patent expires. The purpose of implementing Bolar provision is to provide cheap and affordable generic versions of essential drugs after the patent expires. Until this article was written bolar provisions are only regulated in Article 167 letter b of Law No. 13 of 2016 concerning patents and there are no implementing regulations specifically regulating bolar provision so that bolar provision has not been implemented. Therefore, it is important to examine how the appropriate regulations for the implementation of bolar provision. This type of research is normative legal research. The problem approach used is the legislative approach and the conceptual approach.

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Keywords

Regulation, Bolar provision, Drugs, Patents, Public Health

Introduction

Health is the main factor that must be maintained for the sustainability of life in the world [1]. Global health issues have become issues of common concern [2]. The workshop on medicines created by the Indonesian Ministry of Foreign Affairs, the Regional Workshop on Access to Medicines and Intellectual Property Rights (IPR)

revealed that the existence of patents actually makes the price of some medicines in developing countries expensive [3].

The limited availability of essential medicines puts the government in a difficult situation because in certain cases the government has no choice but to buy expensive medicines from patented drug companies to meet the demands of its people. The government's limited availability of essential medicines results in a decline in the quality of life of the people, even though the government is responsible for the availability of medicines.

The problem of quality and affordability of patented drugs does not only occur in Indonesia. For example, the Indian Case Study against Swiss Novartis AG on the Gleevec Patent, allowed suppliers, healthcare sector and patients to determine price agreements and resulted in the public paying unreasonable prices for a tactic called evergreening i.e. modifying the chemical form, dosage form and other minor modifications that do not significantly improve effectiveness. *drug* new compared to *drug* its parent. This is very detrimental to society [4].

Something similar has also happened in the United States. For example, the price of Hepatitis C drugs in America is very expensive. Hepatitis C can be cured with the patented drug Hepatitis C Gilead which has a cure rate of up to 95 percent. Hepatitis C patients in the United States have to pay more expensive drug prices than in Egypt for the same drug. American patients have to pay more than 1000 dollars, while Egyptian patients pay less than 100 dollars. This happens because of the competition in patented drug prices and price monopolies by drug companies [5].

The high price of patented drugs gives the impression that patented drugs are only intended for people who can afford them. In fact, diseases can attack various levels of society. Patented drugs are not the only drugs that can be consumed by the public, but not all patented drugs are available in generic form, so people still have to buy these patented drugs.

To overcome the high price of patented drugs, the bolar provision concept is used. Bolar provision concept originated from a dispute over patent drug protection that occurred in the United States between the Roche pharmaceutical company Products, Inc with Bolar Pharmaceutical Co., Inc. Bolar is a generic drug manufacturer. Roche is a pharmaceutical company that makes and sells Dalmane, the active ingredient of which is protected by a patent that expires on January 17, 1984. Before the patent expires, to obtain Food and Drug Administration (FDA) approval drug administration for a generic version of Dalmane, in early 1983 Bolar conducted trials on the chemical *flurazepan hcl* in the patented Dalmane sleeping pill to determine whether its generic products were bioequivalent. In July 1983, Roche filed a complaint with the court and attempted to bar Bolar from using the ingredient *flurazepan hcl* for any purpose while the patent has not expired. In October 1983 the court ruled that Bolar's use of the patented compound for federally mandated testing was not patent infringement because Bolar was using it for experiments [6].

Since then, this policy has been known as bolar provision. Bolar provisions are widely adopted in Patent Laws in various countries, for example the United States, Canada, Mexico, Chile, Colombia, Hong Kong, China, Indonesia, India, Malaysia, Japan, Czech Republic, Denmark, Australia and many other countries, but their nature and scope differ significantly from one country to another [7]. Ball Provision is used by many countries because it is considered to be able to meet the community's need for drug availability.

Ball provision gives the opportunity for drug companies to create generic forms of drugs whose patents are about to expire. Drug companies can create branded generics or logoed generics, with the hope that drug prices will be more affordable and the public's right to health will be fulfilled. Bolar provision also limits the scope of patent companies to monopolize exclusive patent rights.

Research methods

This type of research is normative legal research. The problem approach used in this research is the statute approach, conceptual, and comparative approach. Statute approach is an approach that is carried out by examining laws and regulations related to health, medicines and human rights. Conceptual approach is an approach to the legal concept put forward by experts found in various literature regarding the right to health, access to medicines, and human rights based on the constitution [8]. Comparative approach is an activity to compare legal regulations in Indonesia with legal regulations in countries that have regulated ball provision.

Results and Discussion

Legal analysis on fulfillment of public health rights to the availability of patented drugs and essential generic drugs

Fulfillment of health rights is an important aspect in the development of a country. In Indonesia, the right to health is guaranteed by the 1945 Constitution of the Republic of Indonesia Article 28H paragraph (1), which states that everyone has the right to live in physical and spiritual prosperity, to have a good and healthy living environment, and to have the right to receive health services provided by the state. However, the fulfillment of this right to health is not only related to access to health facilities, but also the availability of drugs. There are 2 (two) factors that are consideration in study this, namely [9]:

1. Monopoly of patented drugs often results in the price of patented drugs being very expensive. This can hinder people's access to the drugs they need. Although there are efforts through the Doha Declaration to protect people's health rights, the reality is that TRIPs (Agreement on Trade- Related Aspects of Intellectual Property Rights) are more dominant in protecting the rights of developed countries as rights holders for patented drugs.

2. Essential generic drugs are drugs that are recognized as important to meet the health needs of the community. The existence of essential generic drugs is very relevant in the context of fulfilling the right to health. Generic drugs have the advantage of being more affordable than patented drugs, so they can increase public accessibility to treatment.

In fulfilling health rights, there are four principal elements that must be considered [10]:

1. The availability of health facilities and medical infrastructure, including medicines, must be sufficient for the entire population;
2. Accessibility of health services must be economically and geographically affordable for everyone, and respect the cultural traditions of the community;
3. The quality of health services must meet appropriate standards.
4. Equality of health services must be equally accessible to everyone, especially vulnerable groups in society.

The state has a responsibility to ensure that the right to health is fulfilled, including policies that support the availability of medicines, including essential generic medicines, as well as regulations that ensure that medicines are affordable and of adequate quality.

State responsibilities are regulated in Health Law No. 17 of 2023 which consists of 10 articles namely Articles 6 to Article 16. One of the reason arrange that:

> The central government and regional governments are responsible for planning, regulating, organizing, fostering, and supervising the implementation of quality, safe, efficient, equitable, and affordable Health Efforts for the community (Article 6 of Law/17 of 2023).

Government as provider in access and availability health face a number of challenges as following:

1. Access and affordability of health services;
   a. Access, ensuring that all people, especially vulnerable groups, have easy and equitable access to health facilities. This involves geographic issues (e.g., remote areas), transportation, and infrastructure.
   b. Affordability, the government must strive to ensure that health service costs do not burden the community, especially those with low incomes.
2. Equality of rights in obtaining services. Some groups still face discrimination or difficulties in accessing equal health services [11];
3. The quality of health services must meet appropriate standards including education of medical personnel, infrastructure and management of health facilities;
4. Availability of drugs and medical equipment, dependence on imports of drugs and medical materials is an obstacle;
5. Public awareness, education and health campaigns need to be continuously improved;
6. Central and regional authority. Coordination and synergy between the two levels of government must be maintained so as not to hinder the fulfillment of health rights [12].

Urgency of regulatory arrangements regarding bolar provision of patented drugs in Indonesia

Ball provision refers to a provision that allows generic drug manufacturers to begin preparations before the expiration of a drug's patent. With the presence of bolar provision, generic drug manufacturers can reduce the time required to obtain approval after patent expiration, so that generic drugs can be available on the market more quickly. In some countries, ball regulations provisions have been clearly set out to facilitate the production of generic drugs. Bolar provision become very important concept for set up in regulation medicine in Indonesia due to: *first*, the existence of efficiency that is bolar provision allows generic drug manufacturers to prepare for production before the patent expires. This reduces delays after the patent expires and speeds up the availability of generic drugs. *Second*, access to drugs easier. By speeding up the production of generic drugs, patients can more quickly access more affordable alternatives once patented drugs are no longer exclusive. *Third*, cost savings. Generic drugs tend to be cheaper than patented drugs. Bolar provisions help reduce the research and development costs required by generic drug manufacturers [11].

Not all countries implement principle bolar provision in regulation for access and availability health for his country. This has happened because capacity and capability industry pharmacy each country is different. The impact from implementation provision of ball in industry pharmacy is as following:

1. Access to generic drugs. bolar provision allows generic drug manufacturers to start clinical trials and prepare for generic drug production before the expiration of the original drug's patent. Thus, after the patent expires, the generic drug can be immediately available in the market. This helps increase public access to more affordable drugs [13].
2. R&D efficiency. The pharmaceutical industry faces major challenges in developing new drugs. Bolar The provision allows generic drug manufacturers to speed up the development process by leveraging data and research already conducted by the patent holder. This reduces the cost and time required to develop a generic drug [11].
3. Stimulating innovation. Although sometimes controversial, bolar provisions can also encourage innovation. Patent holders must continue to innovate to stay ahead and maintain exclusivity. Competition from generic drug manufacturers forces patent holders to continue to improve their products.
4. Impact on foreign investment. Bolar Policy provision can affect foreign investment interest in the pharmaceutical sector. Some countries that implement bolar strict provisions may be less attractive to foreign pharmaceutical companies. However, on the other hand, bolar provision can also strengthen the domestic pharmaceutical industry and encourage investment in generic drug research and production.
5. Limitations and debate. Some have criticized bolar provision because it is considered to reduce the incentive for patent holders to invest in research and development. In

addition, the implementation of bolar provisions must be balanced so as not to harm the patent holder excessively.

Indonesia is not a producing country drugs so that availability drug essential for disease chronic is very much needed with price affordable and good quality. With existence bolar provision, then Indonesia has endeavor for provide quick drug essential generic after the patent ended. Things to do be noticed in arrangement provision ball in Patent Law in Indonesia, as following [11]:

1. Regulation and policy. The government has a central role in issuing regulations and policies related to bolar. This includes provisions on when and how generic drug manufacturers can begin clinical trials and production preparations before the expiration of the original drug's patent.
2. This regulation helps regulate healthy competition between patent holders and generic drug manufacturers, and ensures faster access to generic drugs after the patent expires.
3. Stimulating innovation and investment. The government can design incentives to encourage innovation in the pharmaceutical sector. For example, providing research and development support for patent holders. On the other hand, the government must also ensure that regulations are provision does not inhibit investment in research and production of generic drugs.
4. Law enforcement. the government is responsible for ensuring compliance with bolar regulations. provision. This involves monitoring generic drug manufacturers and patent holders. If there are violations, the government must act firmly to maintain a balance between intellectual property rights and the interests of the community.
5. Collaboration with industry and related institutions. The government needs to collaborate with the pharmaceutical industry, research institutions, and universities to ensure effective implementation of bolar provision. Open dialogue with all stakeholders will help identify challenges and find shared solutions [14].
6. Education and awareness. The government can play an important role in raising awareness about bolar provision among drug manufacturers, researchers, and the general public. Education and training campaigns will help ensure better understanding of these regulations.

Ball Provision has been implemented in developed countries, including: United States (US). Bolar provision known as "Hatch-Waxman Act." This provision allows generic drug manufacturers to conduct clinical trials and prepare for production before the expiration of the original drug's patent. According to Hatch-Waxman Act, acts such as making, using, offering for sale, or selling a patented product solely for purposes related to the development and submission of information under federal laws governing the production, use, or sale of animal drugs or biological products are not considered patent infringement (Bolar exemption). The European Union (EU), the interpretation varies across member states. Although there is a legal framework governing bolar provision, there is uncertainty about the scope and interpretation across the EU. The

establishment of the Unified Patent Court Patents Court/UPC) is expected to bring additional harmonization across the region [10].

Japan has a ball provision that allows generic drug manufacturers to conduct clinical trials and prepare for production before the expiration of the original drug patent. implementation and interpretation of bolar provisions in Japan also experienced changes over time. Furthermore, India has a provision for bolar provision that allows generic drug manufacturers to start production preparations before the expiration of the original drug patent. India is known as the largest producer of generic drugs in the world, and bolar provision has played a significant role in facilitating access to more affordable medicines. While Brazil allows generic drug manufacturers to start clinical trials and prepare for production before the expiration of the original drug's patent [10].

Conclusion

Ball The provision gives pharmaceutical companies the opportunity to create generic forms of drugs whose patents are about to expire. so that also can limit the scope of patent companies to monopolize exclusive patent rights. The state has a responsibility to ensure the fulfillment of health rights including policies that support the availability of medicines, including essential generic medicines, as well as regulations that ensure affordable prices and adequate quality of medicines. Bolar Provision is important set up in regulation medicine in Indonesia because own impact Good in availability drug generic, simplify the R&D process, stimulate innovation and investment, increasing collaboration with industry.

References

[1] Soekidjo Notoatmodjo, Health Behavior Science. Jakarta: Rineka Cipta, 2010.
[2] Rahmi Jened, "Competition Law & Policy: The Use and Abuse of IPR," Cooperation between Ministry of Foreign Affairs & South Center/WHO, Jakarta, Sep. 19, 2019.
[3] CNBC Directors, "Expensive Drugs in Developing Countries," CNBC.
[4] NP Rudiany, "Governing Global Health Care: A Case Study of India vis à vis Switzerland's Novartis AG Regarding Patents of Gleevec" Journal of International Relations, vol. 10, no. 1, p. 17, Sep. 2017, doi: 10.20473/jhi.v10i1.3657.
[5] Gaston Kroub, "The Cost Of A Cure: Patent Rights and Drug Prices" DrugPatentWatch, Washington, DC, Aug. 26, 2024.
[6] Justia Us Law, "Roche Products, Inc. Appellant, v. Bolar Pharmaceutical" Justia Us Law, United States, pp. 733–858, Apr. 23, 1984.
[7] Anthony Tridico, "Facilitating generic drugs manufacturing: Bolar exemptions worldwide," WIPO Magazine, 2014.
[8] Peter Mahmud Marzuki, Introduction to Legal Science. Jakarta: Kencana, 2008.
[9] LS Muis, "The Right to Accessibility of Patented Medicines for the Community," Widya Pranata Hukum: Journal of Legal Studies and Research, vol. 1, no. 1, pp. 36–64, Apr. 2019, doi: 10.37631/widyapranata.v1i1.259.
[10] LS Muis, R. Jened, N. Barizah, and GC Tjwan, "State Responsibility for Access and Availability of Patented Drugs for Public Health" Juridika, vol. 38, no. 2, pp. 219–242, 2023, doi: 10.20473/ydk.v38i2.43007.
[11] Lidya Shery Muis, "THE PRINCIPLE OF JUSTICE IN THE PROTECTION OF PHARMACEUTICAL PRODUCTS PATENTS TOWARDS THE FULFILLMENT OF PUBLIC HEALTH RIGHTS," Dissertation, Airlangga University, Surabaya, 2023.

[12] L. Shery Muis, "Accessibility of Pharmaceutical Products Patents for Public Health Through the TRIPs Waiver" Indonesian Journal of Law and Society, vol. 5, pp. 1–115, 2024, doi: 10.19184/ijls.v5i1.38647.
[13] YS Atmaja, B. Santoso, and I. Irawati, "LEGAL PROTECTION OF PHARMACEUTICAL PRODUCT PATENTS DURING GOVERNMENT USE OF PATENTS," Legal Issues, vol. 50, no. 2, pp. 196–208, Apr. 2021, doi: 10.14710/mmh.50.2.2021.196-208.
[14] Y. Mumtazah Al'Amani, A. Anggono, and Tarjo, "The Role of Government in Regulating Salt Trade: Political Dominance Will or Economic Interest? A Review of Actor -Network Theory" Journal of Management and Organization, vol. 15, no. 1, pp. 38–51, Mar. 2024, doi: 10.29244/jmo.v15i1.54205.