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The Parallel Imports of Invention Patents in Pharmaceutical Products

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Abstract

This research was carried out with the aim of knowing the nature of parallel imports, regulations in optimizing parallel imports of pharmaceutical patent products and strategies for using parallel imports in pharmaceutical patent product inventions in Indonesia. This research uses a normative type of research by utilizing a legal research approach and a conceptual approach. The results of this study, namely: 1) Parallel import is an activity of importing patent protected inventions without third party permission to the inventor/patent holder so that the patent holder cannot enjoy the incentives for the exploration process by a third party. This activity is carried out because it is crucial and fundamental in nature, namely the interests of health and is related to human life. This activity is to ensure a reasonable price and fulfill a sense of justice for essential pharmaceutical inventions that are very much needed by humans and can cure diseases. The implication is the lack of a sense of justice for the inventor/patent holder and the inventor/patent holder cannot enjoy the maximum economic benefits and exclusive rights over the third party invention exploration process. However, there are exceptions to minimize losses for inventors/patent holders, namely the doctrine of national exhaustion (earning royalties and economic benefits from the first sale) which upholds Article 19 of Law no. 13 of 2016. 2) importers are required to fulfill administrative requirements such as distribution permits, pharmaceutical industry permits from abroad and SKI Border or Post Border. Regulation of parallel import pharmaceutical inventions is regulated in the TRIPs Agreement, Law No. 13 of 2016, Law no. 36 of 2009, Law no. 17 of 2006, Regulation of the Minister of Trade of the Republic of Indonesia Number 17 of 2021, Law of the Republic of Indonesia Number 20 of 2014, BPOM Regulation Number 15 of 2020 and PerKa BPOMRI Number 24 of 2017. 3). Parallel import strategy for patent pharmaceutical inventions with an obligation to importers to complete administrative requirements to prevent misuse of parallel imports, and in accordance with the provisions of Article 167 letter (a) which states a price determination in order to obtain cheaper prices in the international market and reduce competition. healthy so that consumers can get fair prices and create a sense of justice, adhere to the national doctrine of exhaustion which pays attention to the interests of inventors, and imports in reasonable quantities to foster a sense of justice between inventors and importers.

Keywords: Parallel Imports, Inventions, Pharmacy, Patents.

A. Introduction

A patent is an exclusive right granted by the State to an inventor for his invention in the field of technology, who for a certain period of time carries out his invention himself or gives his consent to other parties to implement it. Patents are granted to protect inventions in the field of technology, one of which is pharmaceuticals. Patent protection for drugs has an impact on very high drug prices and minimal drug availability in underdeveloped and developing countries including Indonesia. so that developing countries where pharmaceutical products are marketed find it difficult to meet the needs of pharmaceutical products in their countries. The high number of sufferers of epidemic diseases and the occurrence of public health emergencies causes the state to feel the need to meet the needs of essential medicines, but the high price of medicines makes the goal of the state to provide access to proper medicines for the community. One of the

efforts to fulfill access to pharmaceutical products that have been protected by patents is to carry out parallel imports. Parallel import practice is actually a disadvantage for pharmaceutical manufacturers because third parties can import patent-protected pharmaceutical products into their country without having to enter into a license agreement with the patent owner so that the right owner does not get royalties from the exploitation of his invention. However, there may be exceptions as long as the special import is carried out in a procedure that does not conflict with the law and takes into account the legitimate interests of the owner or holder of IPR. parallel imports in Indonesia as regulated in Article 167 letter (a) of Law Number 13 of 2016 concerning Patents followed by other regulations from the relevant agencies. The practice of parallel imports is a practice that involves many parties/stakeholders, so there is a high possibility of conflicts of interest between institutions.

B. Method

This research is a normative legal research legal research that examines written law from various aspects, namely aspects of theory, history, philosophy, comparison, structure and composition, scope and material, consistency, general explanation and article by article, formality and binding force of a law. law and the legal language used[1]. The problem approach used in this research is a statutory approach and a conceptual approach. In this study, the primary source of legal material is Law no. 13 of 2016 concerning Patents, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the Doha Declaration. While the secondary legal materials by analyzing the formulation of the problem obtained from legal literature, legal journals, the internet, as well as all legal materials related to the issues discussed and tertiary legal materials obtained from the Big Indonesian Language Dictionary and the Legal Dictionary. The technique of collecting legal materials used is a documentation technique which is carried out by taking an inventory of legal materials in the form of legislation, literature and other legal materials related to the parallel import of pharmaceutical product inventions based on Law no. 13 of 2016 concerning patents and other regulations related to product import activities from several institutions in Indonesia. Analysis of legal materials is carried out if all the required legal materials have been collected, then in the next discussion the legal materials will be processed and analyzed and the legal materials obtained are a truth to try to understand these facts.

C. Results and Discussion

Parallel Import

The definition of parallel import is said to be an import activity of all products that are created not within the authority and sovereignty of a country with or without control from the patent holder, but import activities are carried out by parties other than the importer or distribution actor who has the power. This meaning presents an interpretation that products sent in parallel are products that are not created in the country that imports them, but that these products have the possibility of being created in the importing country and circulated and traded to the international market and then imported back into that country. Parallel import is an activity that marginalizes (harms) the inventor, because the import of inventions, which in this case are pharmaceutical inventions that have been protected by a patent, are without permission and approval by a third party to the inventor/patent holder/licensee which causes the patent holder to not be able to enjoy the incentives. for the prerogative exploration process carried out by third parties as a result of the parallel import activities.

Parallel import activities are carried out for reasons that are crucial, namely health interests and are related to human life. Where as has been explained that the impact of the issuance of patents on pharmaceutical products causes the price of pharmaceutical inventions to be very high and uncompetitive, especially for essential, chronic and epidemic medicines. With the high price of these pharmaceutical inventions, it causes difficulties in accessing these medicines in underdeveloped countries and developing countries including Indonesia, resulting in a health crisis and an international health emergency. So that parallel imports were

[1] Abdulkadir Muhammad, *Hukum dan Penelitian Hukum*, PT. Citra Aditya Bakti, Bandung, 2004, p. 101-102.

carried out as an embodiment of the TRIPs Safeguards, in order to be a solution to the health problems that are currently spreading in fulfilling the needs and ease of access to pharmaceutical inventions in the face of the urgency of public health, where Indonesia is still not optimal in industrial activities and production of essential medicines. chronic and epidemic. Regarding health, this is a fundamental/vertical effect/invention that directly affects human health and life and the sustainability of human life (included in 28 paragraph D of the 1945 Constitution).

In parallel import activities in Indonesia, the object/invention of imported patents is only limited to pharmaceutical inventions because medicines are part of the object of vertical effect/basic human rights, rights to life and health which are primary. This is stated in article 167 letter (a) of the Patent Law and article 30 and article 6 of the TRIPs agreement which is described in article 5 (d) of the Doha Declaration. In addition, parallel imports are carried out with the aim of avoiding deviations and manipulation and monopoly activities carried out by inventors/patent holders, in order to build fair and more competitive business competition. Parallel import objects are original products, of good quality at low prices, as a preventive measure in market price discrimination. This activity is to ensure reasonable prices and fulfill a sense of justice for essential pharmaceutical inventions that are desperately needed by humans and can cure chronic diseases and reduce social disparities between underdeveloped countries, developing countries and developed countries in terms of meeting the needs of essential medicines. Not only that, parallel import activities also serve as protection for the country when currency fluctuations occur in countries that implement currencies in the fulfillment of essential drugs.

On the other hand, there are impacts arising from parallel import activities from the point of view of the inventor/patent holder. For the positive impact, parallel import activities are used as a forum to publish and promote inventions that are considered past in their country to other countries, which according to other countries are considered new. However, as previously explained, parallel import activities are activities that are detrimental to the inventor/patent holder, because the importer/third party does not enter into a license agreement with the patent holder/inventor. The implication is that it affects social aspects concerning the lack of justice for inventors/patent holders for parallel import activities and economic aspects, where inventors/patent holders cannot enjoy economic benefits (incentives and royalties) as well as their exclusive rights to the fullest for the invention exploration process. by third parties/importers. However, there are exceptions to minimize the loss of inventors/patent holders, namely several WTO member countries including Indonesia which adhere to the theory of national exhaustion which in Indonesia, the doctrine refers to article 19 and article 74 of Law no. 13 of 2016, where economic benefits are obtained by the inventor/patent holder during the first sale, because after that the patent holder/inventor has given up control over his invention. In principle, the national of exhaustion merely cuts the matter of utilizing, trading and trading a certain part of the patent invention, while the production and import rights are still protected.

Regulations in Optimizing Parallel Imports of Pharmaceutical Patent Products in Indonesia

Regulations regarding the import of pharmaceutical inventions are regulated in several laws and regulations, namely:

1. Trade Related Aspect of Intellectual Property Rights Agreement

Parallel import activities, based on the TRIPs Agreement, it is emphasized that patent holders receive compensation from the country where the invention was first traded. Parallel import activities to be implemented in a country are allowed under the TRIPs Article 8.1 Agreement which stipulates[2]:

"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, that such measures are consistent with the provisions of this Agreement".

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, Article 8.1. Annex 1C

2. 1945 Constitution as a Guide

The Indonesian state has a very big responsibility for the welfare of its people. This is stated in the preamble to the fourth paragraph of the 1945 Constitution and Article 28C paragraph (1) of the 1945 Constitution which reads:

"Everyone has the right to develop himself through the fulfillment of his basic needs, the right to education and to benefit from science and technology, art and culture, in order to improve the quality of his life and for the welfare of mankind"[3].

Article 28H paragraph (1) of the 1945 Constitution, which reads:

"People have the right to have a good and healthy environment and to get health services. Where health services are enforced by the government of the State of Indonesia which are intended for the people, it is an effort to fulfill the people's health rights.

Article 34 paragraph (3) of the 1945 Constitution which reads:

"The state has a very important role and great responsibility for the fulfillment of health service facilities and infrastructure and public facilities that are efficient and good".

3. Law no. 13 of 2016 concerning Patents

Regarding parallel imports, it is explained in Article 167 letter (a) of Law no. 13 of 2016 which reads[4]:
"The import of 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 imported in accordance with the provisions of the legislation."

The explanation of the article is that parallel imports and Bolar provisions are excluded from criminal provisions and civil lawsuits so that there is no doubt for the party who will take the action. Letter a The exemption from importation of pharmaceutical products as referred to in letter a in this Article is to ensure that there is a fair price and fulfills a sense of justice for pharmaceutical products that are very much needed for human health. This provision can be used if the price of a product in Indonesia is very expensive compared to the price that has been circulating legally in the international market[5].

UU no. 13 of 2016 allows the implementation of parallel imports with two conditions, among others[6]:

a) Imports must be done legally; and
b) Products that will be targeted for parallel imports are products that are proven to be relatively more expensive than the same products sold in the international market.

a. Law No. 36 Year 2009 Regarding Health

Law No. 36 of 2009 concerning Health deals with efforts to improve and assist the community in obtaining health services, the need for medicines, health protection and the use of medicines, proper use of medical devices and protection of addictive substances[7]. Regarding the protection of the use of the availability of essential medicines in Article 98 Paragraph (3), 105 and Article 106 of the Health Law, it is stated that the provisions regarding the procurement, storage, exploration, marketing, expansion of essential medicines and medical devices must comply with quality standards. fulfillment of essential drug products as written in Government Regulations and having distribution permits[8]

[3] Pasal 28C ayat (1) UUD 1945
[4] Pasal 167 huruf (a) UU Paten
[5] Penjelasan pasal 167 huruf (a) UU Paten
[6] Penjelasan pasal 167 huruf (a) UU Paten
[7] Undang-undang Nomor 36 Tahun 2009 Mengenai Kesehatan
[8] Pasal 98 Ayat (3), 105 dan Pasal 106 Undang-Undang Kesehatan

b. Law Number 17 of 2006 concerning Customs

The Directorate General of Customs and Excise in carrying out the function of monitoring drug imports refers to the Regulation of the Food and Drug Supervisory Agency No. 15 of 2020 concerning Amendments to BPM Regulation No. 30 of 2017 concerning Supervision of the Importation of Drugs and Food into the Territory of Indonesia. The Directorate General of Customs and Excise inspects and checks the completeness of administrative, customs and tax requirements for import carried out by importers through the Indonesia National Single Window (INSW) portal. export of goods, so that it is more constructive and contributive and shortens the processing period for the traffic and downstream of export-import goods[9].

c. Regulation of the Minister of Trade of the Republic of Indonesia Number 17 of 2021 concerning Exporters and Importers of Good Reputation

The Minister stipulates Exporters of Good Reputation and Importers of Good Reputation who can be granted ease of Business Licensing[10]. In order to be designated as an Importer in Good Reputation as referred to in Article 2, the Importer must meet the following criteria: a. is a Producer Importer; b. has fulfilled the obligation to report on the realization of all Import Approvals that have been made for each commodity in the last 1 (one) year in accordance with the provisions of laws and regulations; c. obtain a valid status in confirming the status of taxpayers from the ministry that carries out government affairs in the financial sector for the last 2 (two) years; d. implementation of Import of Goods in the last 2 (two) years in accordance with the line of business or nature of business; e. has never been subject to administrative sanctions in the form of revocation of licensing for violations of regulations in the field of Import in accordance with the laws and regulations for the last 2 (two) years; f. not being subject to administrative sanctions in the form of written warnings, suspension of permits or suspension of permits for violations of regulations in the Import sector in accordance with the provisions of laws and regulations; and g. have never been subject to criminal sanctions in the trade sector[11].

d. Law of the Republic of Indonesia Number 20 of 2014 concerning Standardization and Conformity Assessment

Standardization and conformity assessment are means to improve quality, production efficiency, facilitate commercial transactions, establish fair, competitive and honest business competition. The National Standardization Body, hereinafter abbreviated as BSN, is a non-ministerial government agency tasked with and responsible for Standardization and Conformity Assessment. Indonesian National Standard, hereinafter abbreviated as SNI, is the standard set by BSN and applicable in the territory of the Unitary State of the Republic of Indonesia. Standardization and Conformity Assessment aims to[12]:

a) Improve quality assurance, production efficiency, national competitiveness, fair and transparent business competition in trade, business certainty, and the ability of business actors, as well as the ability to innovate technology;
b) Increasing protection for consumers, business actors, workers, and other communities, as well as the state, both from the aspect of safety, security, health, as well as the preservation of environmental functions; and
c) Increase certainty, smoothness, and efficiency of trade transactions of goods and/or services at home and abroad

Business Actors who import Goods are prohibited from trading or distributing Goods that are not in accordance with SNI or SNI numbering[13]. Article 67 Everyone who imports goods who intentionally trade or distribute goods that are not in accordance with SNI or SNI numbering as referred to in Article 25

[9] Peraturan Presiden Republik Indonesia Nomor 10 Tahun 2008 mengenai pemanfaatan Sistem berbasis Elektronik dalam Kerangka Indonesia National Single Window
[10] Pasal 2 ayat (1) Peraturan Menteri Perdagangan Republik Indonesia Nomor 17 Tahun 2021
[11] Pasal 4 ayat (1) Peraturan Menteri Perdagangan Republik Indonesia Nomor 17 Tahun 2021
[12] Pasal 3 Undang-Undang Republik Indonesia Nomor 20 Tahun 2014 Tentang Standardisasi Dan Penilaian Kesesuaian
[13] Pasal 25 ayat (4) Undang-Undang Republik Indonesia Nomor 20 Tahun 2014 Tentang Standardisasi Dan Penilaian Kesesuaian

paragraph (4) shall be sentenced to a maximum imprisonment of 5 (five) years or a maximum fine of Rp. 35,000,000. .000,00 (thirty five billion rupiah)[14].

e. Regulation of the Food and Drug Supervisory Agency Number 15 of 2020 concerning Amendments to the Regulation of the Food and Drug Supervisory Agency Number 30 of 2017 concerning the Control of the Importation of Drugs and Food into the Territory of Indonesia

This regulation was created to support the protection, usability, quality of Drugs and Food distributed to Indonesian territories, so a regulation on inspection of Drug and Food distribution to Indonesian territories is required. In carrying out the import of pharmaceutical products, the importer must have a distribution permit and border SKI or post-border SKI. Article 3 paragraph (3a) states that business actors carrying out border import activities of Drugs and/or Traditional Medicines absolutely have Border SKI at the time of submitting notification of import of goods issued by the authorized institution[15]. The party requesting a Border Import Certificate or Post Border Import Certificate shall carry out document input, both primary documents and supporting documents online on the official website of the SKI Border or SKI Post Border service of the Food and Drug Supervisory Agency, which after that performs other steps for obtain a service level arrangement.

f. Regulation of the Head of the Food and Drug Supervisory Agency of the Republic of Indonesia Number 24 of 2017 concerning Criteria and Procedures for Drug Registration

Based on Article 2 paragraph 1 of the Regulation of the Head of the Food and Drug Supervisory Agency of the Republic of Indonesia Number 24 of 2017 concerning Criteria and Procedures for Drug Registration, the pharmaceutical industry whose pharmaceutical products will be imported into the territory of Indonesia must have a distribution permit by previously carrying out the drug registration process submitted to the Head of the Republic of Indonesia. Referring to Article 15 paragraph 1 that imported pharmaceutical products are carried out by applicants who obtain express approval from the pharmaceutical industry abroad.

g. Mechanism of Importing Pharmaceutical Inventions to Indonesian Territory

Pharmaceutical inventions that will be sent to Indonesian territory with the aim of product expansion are required to have an industrial permit, distribution permit by submitting an application to the Head of the Food and Drug Supervisory Agency in accordance with the provisions laid down in the Regulation of the Head of the Food and Drug Supervisory Agency Number 24 of 2017, Import Certificate Border and Post Border, completing all the requirements of the invention, must complete all matters relating to the import of the invention based on the Regulation of the Director General of Customs and Excise Number PER-16/BC/2016 concerning the implementation instructions for releasing imported goods for use.

After obtaining a distribution permit, the applicant must make a Certificate of Import Border or Post Border, this is stated in article 3 of the Regulation of the Drug and Food Control Agency Number 15 of 2020 concerning Amendments to the Regulation of the Food and Drug Supervisory Agency Number 30 of 2017 concerning the Control of the Importation of Drugs And Food Into Indonesian Territory. Border Import Certificate is a letter of approval for the implementation of import/import activities of Medicines and Traditional Medicines into Indonesian territory with the purpose of inspection of the expansion of Drugs and Food. In order to apply the National Single Window (NSW), in order for importers to obtain a Border Import Certificate, importers carry out electronic registration through the official website of the Food and Drug Supervisory Agency, namely http://e-bpom.pom.go.id to obtain a user name and passwords. Applicants for SKI Border are required to have a Border Import Certificate permit code on Online Single Submission and have a Business Identification Number. Based on article 23 of the Regulation of the Drug and Food Supervisory Agency Number 15 of 2020 concerning Amendments to the Regulation of the Food and Drug Supervisory Agency Number 30 of 2017 concerning the Control of the Importation of Drugs and Food into the Territory of Indonesia, that the party implementing the Applicant for the Certificate of Import

[14] Pasal 67 Undang-Undang Republik Indonesia Nomor 20 Tahun 2014 Tentang Standardisasi Dan Penilaian Kesesuaian
[15] Pasal ayat (3a) Peraturan Badan Pengawas Obat Dan Makanan Nomor 15 Tahun 2020

Border or the Applicant for the Certificate Post Border Imports carry out financing on Non-Tax State Revenue within a maximum period of three days accumulating from the date of sending the request through the Border Import Certificate service page or the BPOM Post Border Import Certificate or the official website of the national single window institution. The applicant is waiting for the Service Level Arrangement which is the service level based on the issuance period of the permit provision and approval or rejection of the application for SKI Border or SKI Post Border for the entry of Drugs and Food which will later obtain an Aju number. Within a maximum period of 6 (six) Hours after the complete documents are received according to the requirements and after payment of non-tax state revenue, the application documents as referred to in Article 15 to Article 21 are evaluated to determine the fulfillment of administrative requirements and requirements for safety, efficacy/benefit, and quality to issue approval or rejection[16]. The approval of the SKI Border application is issued in electronic form, does not require a wet stamp and signature[17].

4. Strategy for Using Parallel Imports in Pharmaceutical Patent Product Inventions in Indonesia

Strategy is a number of integrated and coordinated actions taken to utilize core competencies and gain competitive advantage. A company's success, as measured by strategic competitiveness and high profitability, is a function of the company's ability to develop and use new core competencies more quickly than competitors attempt to emulate existing advantages[18]. In optimizing parallel import activities in Indonesia, several steps have been taken so that parallel import activities can be implemented properly. Although there are still many shortcomings in this activity, at least it can be minimized by monitoring each implementation. The rules and conditions that must be fulfilled by parallel importers are clearly stated in the implementation of parallel imports. In Article 167 letter (a) of the Patent Law, it is stated that the absolute requirement is that the price of inventions is higher in the domestic market compared to the price of similar inventions circulating in the international market. create a sense of justice. Article 167 letter (a) of the Patent Law places more emphasis on the object of import, which the object of import must meet the requirements and be original goods. Some of these conditions include having an industrial permit, distribution permit, Border SKI or Non-Border SKI issued by institutions related to import activities. These administrative requirements are the government's steps as a preventive measure against the misuse of parallel imports, as written evidence that the object of import is genuine goods, safe for circulation and consumption, does not contain hazardous materials, and the price is strictly in accordance with the provisions of article 167 letter (a). . In short, it is a product that deserves to be imported in parallel, in accordance with applicable regulations. In the process of fulfilling the administrative requirements, this activity utilizes the INSW and Online Single Submission forums to simplify and streamline time. In addition, before carrying out parallel import activities, Indonesia sent a surveyor team overseas (country of origin of the parallel import object) whose surveyor team came from the Ministry of Foreign Trade to physically inspect the products to be imported, processing processes in the form of sanitation, hygiene, production methods, tools and materials/composition used, then enter Indonesia according to the agreement and are re-inspected in the form of samples (drugs and food) by BPOM regarding the effect on public health, efficacy, benefits, quality, fit for circulation, harmful or no, the content is safe or not. BPOM is issued a distribution permit based on evidence if it meets the clinical trial requirements (ML = foreign product and MD = domestic product). After that, certain quantities of goods (as needed) are imported to Indonesia and then connected to the Directorate General Customs and Excise, then goods enter Indonesia and drug circulation is carried out. Supervision is not only when goods enter, but also a market supervision, public consumer protection agency, BSN (National Standardization Agency) and Domestic Trade. For a strategy with the involvement of these

[16] Pasal 23 Peraturan Badan Pengawas Obat Dan Makanan Nomor 15 Tahun 2020 Tentang Perubahan Atas Peraturan Badan Pengawas Obat Dan Makanan Nomor 30 Tahun 2017 Tentang Pengawasan Pemasukan Obat Dan Makanan Ke Dalam Wilayah Indonesia

[17] Pasal 24 Peraturan Badan Pengawas Obat Dan Makanan Nomor 15 Tahun 2020 Tentang Perubahan Atas Peraturan Badan Pengawas Obat Dan Makanan Nomor 30 Tahun 2017 Tentang Pengawasan Pemasukan Obat Dan Makanan Ke Dalam Wilayah Indonesia.

[18] Hitt michael, dkk, *Manajemen Strategis*, Erlangga, Jakarta,1997, p. 137.

various institutions as well as the obligation of importers to complete various administrative requirements such as distribution permits, industrial permits, SKI brorder/Post Borders, it aims to protect the authenticity and quality of these products, thus avoiding the thought of the entry of goods with the distribution method. which is not clear (illegal) and can change the negative connotation of "gray market".

In addition, because parallel import activities are actually activities that are detrimental to the inventor, this activity is in accordance with the provisions which are absolutely restrictive to the price of the invention, which means that not all patent-protected inventions can be used as targets for parallel imports, only certain drugs. which is very important for the survival of human life and is primary and fundamental to human life. Moreover, the State of Indonesia adheres to the national doctrine of exhaustion which protects and pays attention to the interests of inventors. The National of exhaustion only curtails the right to use, trade, and trade certain parts of the invention. Meanwhile, the right to produce and import by the patent holder is still protected in the national doctrine of exhaustion. This doctrine adheres to Article 19 of the Patent Law. exhaustion theory itself is a theory of the release of rights after the first sale (earning royalties and economic benefits from the first sale) as an effort to minimize the imbalance of rights between patent holders/inventors and importers/countries carrying out parallel imports.

Parallel import activities themselves are carried out with strong and significant reasons. Namely in the interest of public health welfare and addressing public health emergencies. It is necessary to increase the target of parallel import of patent inventions, to optimize the performance and utilization of parallel imports. However, it must be in a reasonable amount, not excessive (not on a large scale). This is to foster a sense of justice and balance between inventors and importers. The government in carrying out parallel import activities is carried out with full consideration, the choice of this flexibility is adjusted to the needs and conditions of the country. Parallel import is said to be a type of flexibility that is easier to apply compared to other flexibility, where each flexibility in The TRIPs Safeguards has its own advantages and disadvantages according to needs. The flexibility offered and permitted include government use, compulsory licensing and provision bolar. The three types of flexibility, parallel import in terms of the process is said to be the easiest and possible to be carried out in a short time. Because both government use, compulsory licensing and provisional licensing are directly related to product industry activities carried out by a country without permission from the patent owner, with the aim of a country being able to manufacture its own products which are expected to produce lower prices compared to other countries. import prices and avoid Indonesia's dependence on imported goods. However, this is not an easy thing to do, because it requires a lot of process, cost and time and does not forget to pay attention to the interests of the patent owner, because the three flexibilities are flexibility that is obliged to give royalties to the patent owner. However, in the end, the three flexibilities have not been fully implemented as expected and there are still many shortcomings in their application. As regarding prices, for example, there are several essential medicinal products whose prices are still more expensive than imported drugs due to limited raw materials, human resources and the provision of royalties for patent owners. one of the state-owned companies appointed to carry out government use, compulsory licensing and bolar provision, namely PT. Kimia Farma, which produces generic versions of patented drugs. One of them is AIDS drugs. If various improvements and preparations have been made, in the long term it can implement the flexibility of Bolar Provision, government use and compulsory licensing as flexibility that is directly related to the activities of the pharmaceutical industry for generic versions of patented drugs so that they do not depend on imported products.

D. Conclusion

Parallel import is the activity of importing patent protected inventions without the permission of a third party to the inventor/patent holder so that the patent holder cannot enjoy the incentives for the prerogative exploration process carried out by a third party. Parallel import activities for things that are crucial and fundamental, namely the interests of health and related to human life and in Indonesia, the object of parallel import of patent inventions is only for pharmaceutical products, as evidenced in the Patent Law article 167 letter (a) and article 30 and article 6 of the agreement. TRIPs described in article 5(d) of the Doha

Declaration. This activity is to ensure reasonable prices and fulfill a sense of justice for essential pharmaceutical inventions that are desperately needed by humans and can cure diseases. The implications are in the social aspect due to the lack of a sense of justice towards the inventor/patent holder and the economic aspect, where the inventor/patent holder cannot enjoy maximum economic benefits and exclusive rights over the exploration process of third party inventions. However, there are exceptions to minimize losses for inventors/patent holders, namely the doctrine of national exhaustion (earning royalties and economic benefits from the first sale) which upholds Article 19 of Law no. 13 of 2016 (protecting/prohibiting production and import activities).

Before carrying out parallel import activities, importers are required to fulfill administrative requirements such as distribution permits, pharmaceutical industry permits from abroad and SKI Border or Post Border. The procurement of pharmaceutical inventions is regulated in the TRIPs Agreement, the 1945 Constitution as a guide, Law no. 36 of 2009 concerning Health, Law no. 17 of 2006 concerning Customs, Regulation of the Minister of Trade of the Republic of Indonesia Number 17 of 2021 concerning Exporters and Importers of Good Reputation, Law of the Republic of Indonesia Number 20 of 2014 concerning Standardization and Conformity Assessment, BPOM Regulation Number 15 of 2020 concerning Amendments to BPOM Regulation Number 30 of 2017 concerning Supervision of the Importation of Drugs and Food into Indonesian Territory and PerKa BPOMRI Number 24 of 2017 concerning Criteria and Procedures for Drug Registration.

The parallel import strategy for patent pharmaceutical inventions with an obligation to the importer to complete administrative requirements is a government step as a preventive measure against the misuse of parallel imports, and in accordance with the provisions of article 167 letter (a) which states a price determination in order to obtain a cheaper price on the international market. and reduce monopolies and unfair competition so that consumers can get fair prices and create a sense of justice, adhere to the national doctrine of exhaustion which protects and pays attention to the interests of inventors, imports in reasonable quantities to foster a sense of justice and balance between inventors and importers and utilize INSW and Online Single Submission in import administration. If various improvements and preparations have been made, in the long term it can implement the flexibility of Bolar Provision, government use and compulsory licensing as flexibility that is directly related to the activities of the pharmaceutical industry for generic versions of patented drugs so that they do not depend on imported products.

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