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Intellectual Property and Public Health Emergency: Bolar Provision and Parallel Import

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ABSTRACT

Parallel import and Bolar provisions are excluded from criminal provisions and civil lawsuits. Bolar provision is a policy that allows third parties to test, use and make patented drugs for the purpose of seeking approval from the Food and Drug Administration before the patented drug expires. This provision aims to provide opportunities for the national pharmaceutical industry to conduct further research and development, testing for production, and product registration in the period before the expiration of its patent period. Parallel imports are exceptions to be penalized or sued for the importation of patent-protected pharmaceutical products into a country without the permission of the patent owner and patent holder in the country of origin. It aims to provide an opportunity to get better access to cheaper and more affordable pharmaceutical products. Both provisions are an exception to the exclusive rights owned by the patent holder. However, in practice, such provisions are not necessarily possible. The regulations are so brief and not detailed that it requires interpretation in the process. Therefore, this study will try to find a solution to why the regulations that exist can not be applied in practice. The method of this research is normative legal study. The study found that the implementing rules of the provisions of Bolar and parallel imports are required. Although there has been an implementing rule on drug registration, in practice, the rule still does not protect the rights of patent holders.

Keywords: *intellectual property rights, Bolar provisions, parallel imports, generic drugs, patents*

1. INTRODUCTION

Patents are exclusive rights granted by the state to inventors for the results of their inventions in technology for a certain period of time carry out the production of the invention for themselves or giving approval to another party to do it. Anyone without the patent holder's consent is prohibited from making, using, sell, import, rent, deliver, or provide for sale or rent or submitted the product which was granted a patent.

Bolar provisions are policies that allow third parties to test, use and manufacture patented drugs for the purpose of seeking approval from the Food and Drug Supervisory Agency (BPOM) before the patented drug expires. The testing, using, and manufacturing process of patented drugs is for marketing approval only, not for commercial activities.[1][2]. The provisions for Bolar exceptions at the national level in Law no. 13 of 2016 concerning Patents are contained in Article 167 (b), and at the international level, it is contained in Art. 30 TRIPS.

This provision is an exception to being criminalized or being sued for the use of a patent for a pharmaceutical product within 5 (five) years prior to the end of the patent period. The 2016 Patent Law regulates 5 (five) years before the patent expires.

The legal basis for implementing regulations is contained in Articles 12 and 13 of Ministry of Health Regulation No. 1010 of 2008 concerning Drug Registration (and its amendments) and Articles 20 and 21 Regulatory Chief BPOM No. 24 of 2017 concerning Criteria and Procedure for Drug Registration (and its amendments). This provision aims to provide an opportunity for the national pharmaceutical industry to carry out further research and development, testing for production, and product registration in the period before its patent expires.

Several issues regarding Bolar provisions in the Patent Law, namely:

a. The regulations on Bolar provisions under the Patent Law are very vague and inadequate.
b. Bolar provisions should be stated explicitly in the body text of the Patent Law.
c. The provisions of Article 167 (b) do not explain the need to implement regulations related to drug registration at the ministerial or agency level.
d. Provisions are very limited on the production of pharmaceutical products within a certain period and purpose, which is drug registration.

Parallel import is an exception to be criminalized or sued for the import of patent-protected pharmaceutical products into a country without the permission of the patent owner and patent holder in the country of origin. It aims to provide opportunities for better access to cheaper and more affordable pharmaceutical products.[3][4].

Several issues regarding parallel imports in the Patent Law, namely:

a. Regulations on parallel imports are very brief and not detailed.

b. The provisions of Article 167 (a) do not explain the need to implement regulations related to drug registration at the ministerial or agency level.
c. The scope of Article 167 (a) is limited to 'pharmaceutical products.
d. What about the first sale doctrine on importation exemptions for pharmaceutical products?

2. RESEARCH METHOD

This research is conducted using a normative legal study, which analyzes both primary and secondary data. The primary data is any regulations concerned with Bolar provision and parallel import, while the secondary data consists of literature, journals, and dictionaries related to the problems that persisted in this research. Thus, this research does not only compile the materials such as theories, concepts, principles, and regulations of law dealing with the topic but also explains the reality of the law in society as a law phenomenon for the subject, that is the need for cheaper drugs by granting access to patented drugs. All data needed are collected by literature review.

That data, then, are analyzed by comparing with the case study as the baseline. The case study is needed to give context and recommendations. The case study is chosen purposively from various countries to compare the different systems of law.

3. FINDINGS AND DISCUSSION

Bolar provisions and parallel import are part of TRIPS flexibilities. Member states of WIPO administered treaties enjoy an important degree of room for maneuver in the implementation of their obligations. Some experts believe that the foundation of the available flexibilities is found in the TRIPS Agreement's negotiation process.[5]

Moreover, the term “flexibility” is contained in certain provisions such as paragraph 6 of the Preamble of the TRIPS Agreement:

> “[...] the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.”

The meaning of the word “flexibility” as used in the Preamble is explained by Article 66.1, which reads:

> “In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of...”

Thus, flexibilities are derived from the normal exercise of treaty implementation. All treaties provide options for countries’ decisions and choices when implementation is undertaken.[6]

In addition, the countries’ decisions and choices related to patents can be seen in terms of morality and public order. Countries have the right to protect the public interest, and patent law is not an exception to this general principle. Based on a long-established tradition in patent law (particularly in the European context), TRIPS allows (but not mandates) two possible exceptions to patentability based on public order and morality. The implementation of these exceptions, which need to be provided for under national law in order to be effective, means that a WTO Member may, in certain cases, refuse to grant a patent when it deems it necessary to protect higher public interests.[7]

1. The Perspective of Law

a. The Concept of Bolar Provision

As referred to in the Bolar provisions, exceptions are to guarantee the availability of pharmaceutical products by other parties after the expiration of the patent protection period. Thus, reasonable prices for pharmaceutical products can be pursued. The terminology is not unanimous in how to call this concept: in some cases, the expression used is "research exemption," in others "research exception" and in others "experimental use exception"; it is thus proposed to use the expression contained in the law of a given country or in a cited case law.

A significant number of countries worldwide provide in their national laws the so-called research exemption. Others have developed this exception through their case law. Therefore, it is not surprising that in the Canada Patent Protection of Pharmaceutical Product case (DS114), the WTO Dispute Settlement Panel has referred to the research exemption as “one of the most widely adopted Article 30 type exceptions in national patent laws”.[7]

The panel in the Canada-Patent Protection of Pharmaceutical Products case defines the research exemption as follows:

> “the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement."

The rationale of the exception was explained in the Canada-Patent Protection of Pharmaceutical Product in the WTO Dispute Settlement Panel decision:

> “… this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a ‘legitimate interest’ in using the patent

> disclosure to support the advance of science and technology."

The research exception is also known as the "Bolar exception," after a well-known 1984 US case, Roche Products v Bolar Pharmaceuticals. The Court of Appeals for the Federal Circuit ruled that the research exemption did not cover Bolar's acts to carry out equivalency tests for the regulatory approval of generic medicines before the expiration of the relevant patent owned by Roche.

Despite the fact that Bolar Pharmaceutical's use was not considered covered by the general research exemption, and in consequence, it lost the case, the concern that this case generated was brought to the US Congress. It decided that it was not appropriate to prevent generic pharmaceutical manufacturers from preparing and obtaining regulatory approval for their generic products since it would delay the entrance of generic medicines on the market for a substantial period, extending the effective protection period beyond the patent term. Consequently, an explicit exception was introduced in the US patent law (35 USC 271(e)(1)).

The Bolar type exception contained in the Canadian Patent Law (Art.55.2 (1)) has been studied by a WTO panel, which found that this norm was in line with the TRIPS Agreement, particularly with Article 30. In the panel's view, this exception is "limited" for the following reasons:[8]

> "…because of the narrow scope of its curtailment of Article 28.1 rights. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products…."

With the notable exception of Hong Kong, China, Bolar-type exemptions are prevalent in the national patent laws of many Asian countries. For example, Pakistan (Section 30(5)(e) of the Patents Ordinance 2000) provides Bolar-type provisions for research intended to be submitted to authorities in the country, while Section 107(a) of the Indian Patents Act more broadly exempts acts relating to the development and submission of information required by law "in India or in a country other than India." In contrast, the scope of the Bolar defense is narrower in Singapore (Singapore Patents Act, Section 66(2) h) and is limited to clinical testing to meet requirements for marketing approval in that country alone.[9]

b. *The Concept of Parallel Import*

The exclusion of importation of pharmaceutical products as intended in this article is to guarantee its existence prices are reasonable and meet the sense of fairness of pharmaceutical products, which is very much needed for human health. This provision can be used if the price of a product in Indonesia is very high compared to the price that has been circulating legally in the international market.

Parallel imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner or with the patent owner's permission in one country and imported into another country without the approval of the patent owner. For example, suppose company A has a drug patented in the Republic of Indonesia and Singapore, which it sells at a lower price in Singapore. If a second company buys the drug in Singapore and imports it into Indonesia at a lower price than company A's, that would be a parallel import.

The legal principle here is "exhaustion," the idea that once company A has sold a batch of its product, its patent rights are exhausted on that batch, and it no longer has any rights over what happens to that batch. The TRIPS Agreement simply says that none of its provisions, except those dealing with non-discrimination, can be used to address the issue of Exhaustion of intellectual property rights in a WTO dispute. In other words, even if a country allows parallel imports in a way that another country might think violates the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved.

Under English common law,[10]

> "It is open to the patentee, by virtue of his statutory monopoly, to make a sale *sub modo,* or accompanied by restrictive conditions which would not apply in the case of ordinary chattels; ... the imposition of these conditions in the case of sale is not presumed, but, on the contrary, a sale having occurred, the presumption is that the full right of ownership was meant to be vested in the purchaser while ... the owner's rights in a patented chattel would be limited, if there is brought home to him the knowledge of conditions imposed, by the patentee or those representing the patentee, upon him at the time of sale."

Continental law follows a different philosophy in order to determine the limits of intellectual property rights. Instead of theoretically allowing the owner of such right to impose contractual conditions upon the sale of protected products, continental law rather assumes absolute limits of intellectual property rights that can be described as the principle of Exhaustion. Unless otherwise stated in the law, the economic exploitation of intellectual property rights is limited to the act of the first sale. Further contractual conditions would thus be null and void. Exhaustion is thereby assumed even without any particular mention in the law itself.[11]

The doctrine of Exhaustion means that an owner of a particular good ceases to have control over the further sale of his goods once he has made a valid transaction of sale.

Hence, this doctrine is also called the doctrine of the first sale. Therefore, the positive impact of parallel importation is that it forces prices down and provides consumers with goods at lower prices.

The criteria of "legally marketed" in the foreign country are unclear, however. The Indonesian parallel import provision is not tied to the concept of consent from the IP owner in the overseas market. As a result, the term “marketed legally” might unintentionally include situations wherein a product is marketed legally for other reasons, such as when the patent holder did not file a patent in that country or because of compulsory licensing.

2. The Perspective of Rights

a. Considering the Public Health Emergency

Some governments were unsure of how these TRIPS flexibilities would be interpreted and how far their right to use them would be respected. The African Group was among the members pushing for clarification. A large part of this was settled at the Doha Ministerial Conference in November 2001. In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement to support public health, which promotes both access to existing medicines and the creation of new medicines.[12]

Therefore the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities built into the TRIPS Agreement, including parallel importing. On one remaining question, they assigned further work to the TRIPS Council to sort out how to provide extra flexibility so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries.

One of the key questions is how to balance the interests of patent-owning pharmaceutical companies in developed countries in light of deteriorating public health in developing countries, especially during public health emergencies such as covid-19. Paragraph 4 of the Doha Declaration prioritizes public health over IP rights and clarifies that this extends to medicines and vaccines, diagnostics, and other health tools as required.

In an attempt to priorities public health, in June 2020, the World Health Organization (WHO) established the Covid-19 Technology Access Pool (C-TAP), which aims to gather patents and all other forms of intellectual property in order to expand the development and production of new technologies needed in its response to the pandemic. However, C-TAP is a voluntary mechanism and does not force those who own the rights and knowledge to collaborate.

Essentially, patents afford the privilege of incentivizing new innovation for the benefit of society. That goal is achieved through the grant of monopoly for a limited period in order to sustain the engine of innovation that should drive development. This underlining essence of a patent is important to public health objectives but involves a complex dynamic of IP as an innovation policy.

On 2 October 2020, communication from the Indian and South African delegations noted that the Covid-19 pandemic placed significant strain on importing and exporting several essential pharmaceutical equipment and medicine. As a result, certain developing nations were experiencing difficulties in obtaining resources as wealthy nations used protectionist measures to safeguard existing medical supplies.

The TRIPS waiver proposal, therefore, sought to waive Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement, as well as Article 31. Indonesia has publicly announced its support for the proposed TRIPS waiver, recognizing the many difficulties that developing countries could experience when attempting to address both medical shortages and affordability of drugs, vaccines, and equipment.

Indonesia noted that the waiver provided a "different perspective…by addressing one of the core challenges in rapid, equitable and affordable access to health." They also recounted the significant difficulties it faced in obtaining the anti-viral medication, Remdesivir, which has been widely used to treat Covid-19 patients. This was largely a result of unsuccessful voluntary licensing negotiations, with importing the drug being highly challenging due to the high price and limited supply. [13]

According to WTO [14], members who can implement flexibilities in a timely manner should continue to do so. Furthermore, those Members who think that TRIPS flexibilities are enough for COVID-19 response and they do not need the waiver can choose not to implement the waiver in their domestic legislation. Thus, the waiver is more than just a legal mechanism; it is a statement of intent by all countries that they accord the highest value to protecting human lives rather than protecting private profits.

b. Considering the Intellectual Property

Pharmaceutical parallel imports are the completely legal activity of importing patent-protected drugs into another country where the same product has been registered and is marketed without the patent holder's consent. IP rights holders are, by definition, monopolists who would like to set prices in different markets with different elasticities of demand in a manner that allows them to obtain the highest profit possible. If the monopolist can maintain geographical market segmentation, he can charge higher prices in markets with lower demand elasticity. Parallel imports counteract this ability and lead in theory and on competitive, unregulated markets to uniform pricing.

One of the key points in the discussion about parallel trade is the research-based industry's argument that lost profits from parallel imports affect investments in R&D and incentives negatively. Innovations in pharmaceuticals concern mainly the discovery and development of new chemical and biopharmaceutical entities that become new

therapies. R&D is a very costly and lengthy process of which the fruits cannot be fully yielded for many years.[15]

On the other hand, an increase in generic sales also signifies a decrease in sales of original products as generics are prescribed as substitutes after the patent protection period is over. Since their prices are, in general, significantly lower than those of original products, they add to important savings in pharmaceutical spending. Moreover, generic substitution is often required by law. For example, substitution by cheaper products refers equally to parallel import products and generics.

During the COVID-19 pandemic, the United States experienced shortages of needed drugs and medical equipment. Some state governments could broker deals with foreign governments and import needed personal protective equipment and medical devices. But when it came to obtaining scarce patented drugs, states had few options. The federal government may produce patented goods without permission and under the background principles of the US Constitution and the Eleventh Amendment; states enjoy sovereign immunity and cannot be sued by private parties for damages when they violate federal law.[16]

Although Congress can waive state sovereign immunity under the Fourteenth Amendment, a prior attempt to do so for patent infringement was declared unconstitutional by the Supreme Court. As a result, patent holders are currently unable to sue state infringers for damages. This protection presents an opportunity for states to alleviate shortages of patented drugs during public health emergencies. States could attempt to import patented drugs or produce drugs themselves and then use their sovereign status to shield against damages.

In the EU, a Community-wide Bolar exemption was introduced by the pharmaceutical review. Before, the development and testing work required to make an application could only take place after the patent expiry, resulting in delays of around two years. According to the European Generic Medicines Association (EGA): "In an era when increasing demands are being made on Europe's healthcare services, generic medicines provide a major benefit to society by ensuring patient access to quality, safe and effective medicines while reducing the cost of pharmaceutical care."[17]

From a public health perspective, it is of utmost importance that the national legislation contains multiple safeguards. "Bolar" provision creates conditions that allow generic manufacturers to start marketing their product immediately upon expiry of relevant patents. Parallel importation works most effectively when countries adopt an "international exhaustion" regime, thus allowing the imports of patented products marketed anywhere in the world. Thus, like a "Bolar" provision, parallel importation is usually incorporated in the section of the law that deals with exceptions to the rights conferred by a patent.

4. CONCLUSION

Based on the discussion above, it is clear that bolar provision and parallel import are essential for public health emergencies. Both policies are part of the TRIPS flexibilities that Indonesia should use to provide access to cheap and affordable medicines for the public. Furthermore, the Bolar provision policy that provides access to patented drugs before the patent expires needs to be made in implementing regulations to ensure legal certainty. The Bolar provision that already exists in the Patent Law does not adequately guarantee the implementation of access to these cheap drugs. Therefore, the recommendation is that the words 'Bolar Provisions' are included in the body text of the Patent Law so that there is consistency in the use of the word 'Bolar Provisions' with the Explanation of the Patent Law.

In practice, the application of Bolar provisions should be supervised by government regulations that include requesting approval from BPOM. Supervision of Bolar provisions needs to be tightened to provide legal protection to the patent holder. The implementation of Bolar provisions needs to be strengthened by determining the type of generic version of the drug. Potential pharmaceutical candidates for Bolar provisions must be selected using a transparent process.

The scope of parallel imports needs to be considered as expanding beyond just 'pharmaceutical products' into generally speaking 'health products' to include parallel imports for nutritional products and personal protective equipment (PPE), for example, a ventilator. In terms of the first sale doctrine, it excludes parallel imports from criminal sanctions and civil suits and makes the right holder's import rights expire after the first sale of pharmaceutical products.

Finally, considering the Patent Law only regulates patent exemptions (Parallel Imports and Bolar Conditions) in general at Article 167, it is recommended to add the article which states that 'Further provisions regarding Parallel Import and Bolar Provisions shall be regulated by ministerial regulations or related agency regulations which organizes drug import and registration affairs.'

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