

GOVERNANCE AND REGULATION OF LOCAL WORKING REQUIREMENT AND IMPORTATION: PHARMACEUTICAL INDUSTRY STUDY

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Abstract

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This paper aims to analyze the governance and regulation of local working requirement (LWR) and importation of pharmaceutical products in Indonesia. Based on the theoretical perspectives of Cottier and Panizzon (2004) and Champ and Attaran (2002), this study aims to analyze the important role of patents through LWR and importation, both directly or indirectly to facilitate the transfer of technology and to stimulate technology transfer with the availability of technology information through patent documents. The research was conducted by using a qualitative descriptive-analytical method. A doctrinal approach was used in this study in the context of reviewing the laws and regulations in the field of patents, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS Agreement), health law, and its derivative regulations. The theory used in this study is about the politics of patent law which focuses on the national interest to pursue local production of patented inventions. The results showed that LWR, pharmaceutical importations provisions, and intellectual property rights law policies as a whole in Indonesia need to be harmonized and integrated with policies on technology transfer, industrial development, trade, and investment. The results underscore the main way in which LWR can contribute directly to the transfer of technology in developing countries.

Keywords: Governance, Regulation, Local Working Requirement, Importation, Pharmaceutical Products, Indonesia

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1. INTRODUCTION

The manufacture of products or the application of processes from patents to local industries is generally referred to as local working requirement (LWR). As a reference in international law, Article 7

of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS Agreement) stated that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and

dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations (Oguanobi, 2018; Contreras, Lakshane, & Lewis, 2018; Roisah, Rahayu, Darminto, & Suryani, 2021). Moreover, Article 8 of the TRIPS Agreement stated that members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement. In addition, appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology (Manu, 2015).

LWR is to ensure that the exclusive rights granted through patents generate economic benefits for the grantor of the jurisdiction (Saha & Kaushik, 2021; Bonadio, 2012; Trimble, 2016). While patents are seen as creating incentives for inventors to share ideas, LWR is intended to reduce the exclusivity of the patent monopoly by requiring patent holders to disseminate their inventions to the local market. Patent holders thereby impart knowledge and skills to local communities, promote economic growth, support local manufacturing, and promote the introduction of new product innovations into local markets (Day & Schuster, 2019; Roisah, Setiyono, Prananingtyas, & Farida, 2017). The assumption is that local production of patented inventions will reduce transportation costs, cut reliance on foreign suppliers, provide local jobs, increase expertise, lead to technology transfer and lead to innovation (Ferrucci, 2020). It also confirms that it will help the nation achieve economic independence and sustainable development (Rao & Guru, 2003; Drahos, 1998). In most industrialized countries, intellectual property rights, particularly the exploitation of patents by domestic industries, play a key role in the development and commercialization of new products. This paper aims to analyze the governance and regulation of LWR and importation of pharmaceutical products in Indonesia. Patents indirectly play an important role in the facilitation and transfer of technology. Information technology through patent documents can facilitate and stimulate technology transfer. In this case, the research analyzes LWR and imports, which are considered crucial as facilitators towards technology transfer. Theoretically, this study refers to the theoretical perspectives of Cottier and Panizzon (2004) and Champ and Attaran (2002).

The structure of this article is divided into several sections. Section 1 is the introduction that indicates the literature gap, research aims and questions, and the relevance and significance of the study. Section 2 is the literature review that comprehensively discusses the theoretical and conceptual framework applied by basing it on several relevant theoretical frameworks in patents, LWR, and importation of pharmaceutical products. Section 3 is the methodology that discusses the design and approach used in the study. Section 4 discusses the main findings regarding governance and national policies of LWR and the importation of

pharmaceutical products. Section 5 discusses the results of this study complying with previous studies and discusses the rationalization of the findings. Section 6 concludes the article and explains the theoretical contribution of the findings, practical implications, research limitations, and directions for future research.

2. LITERATURE REVIEW

In general, LWR means practicing, in some way, an invention that is patented in the country that issued the patent. LWR can be achieved by direct investment, joint ventures, or through exclusive or non-exclusive licensing contracts. LWR relates to the condition that some countries impose on patent recipients that the patented product or process must be used or produced in the patent granting country (Innocenti, Capone, & Lazzeretti, 2020; Reddy & Kadri, 2013). This condition has the effect of forcing foreign patent recipients to locate production facilities in the country where the patent is registered (Mossoff, 2001; Hale, 1976). In this case, the patent granting country wants technology transfer which is later expected to contribute to related public policies such as job creation, industrial and technological capacity building, the balance of the national balance of payments, and economic independence (Yang, Matsuura, & Ito, 2019; Antons, 2017; Champ & Attaran, 2002).

LWR is adopted by the state and corresponded to the state's initial approach to its patent system, which was guided by the idea that patents were expected to serve domestic industry (Hrdy, 2013; Reddy & Kadri, 2013). LWR is believed to be useful for technology transfer and the country's economic growth (Drivas, Economidou, Karamanis, & Sanders, 2020). Therefore, it is the primary and fundamental obligation of the patentee to manufacture the patented invention within the territory and always remains a prerequisite for granting the patent (Champ & Attaran, 2002). LWR is basically designed in such a way that it reflects micro- and macro-economic considerations based on international principles of division of labor, research, development, and production. Mandatory local work in the traditional sense, i.e., requiring patented inventions to be produced in the patent granting country is an old mechanism that is no longer in line with today's reality (Cottier & Panizzon, 2004). It is undeniable that protection is inseparable from the trade aspect. The current trading environment is characterized by so-called component trading, not trading in finished commodities. Supply chains are increasingly geographically diversified and commodities are manufactured worldwide producing a sizable number of patented products for wider regional marketing. Therefore, different markets in these regions can be supplied affordably through imports than through licensed domestic products (Abbott & Reichman, 2020). So that imports can meet the LWR partially or completely because the LWR is intended to benefit the public rather than the patent holder, and the public benefits of these requirements are not only measured in terms of domestic manufacturing (Pinto, Vallone, & Honores, 2019; Taubman, Wager, & Watal, 2020). Theoretically, LWR needs to take into account the supply of the domestic population as well as any economic reasons where the LWR is not of many benefits to the local community (Gamharter, 2004).

LWR is not possible in all cases as all inventions may not prove to be economically efficient due to lack of demand/market or interest; in such case the patent holder cannot be burdened with obliging invention work (Reddy & Kadri, 2013). However, such scenarios fall under the exception of working on an invention, if any, for valid reasons. Further, requests for mandatory licenses from local producers are to be expected only if the invention is economically efficient because the granting of such licenses is also subject to royalty payments. Therefore, the question of burden and inconvenience for the patent holder does not arise in the case of the need for LWR. The reasons for this consideration in LWR legal policies in several countries including Indonesia are exceptions and some make importation part of the implementation of LWR.

3. METHOD

The study is conducted by using a doctrinal approach, namely examining the principles of norms, concepts, and doctrines that develop in legal thinking, using a statutory approach, a conceptual approach and the data used are secondary data. The doctrinal approach in the context of reviewing the laws and regulations in the field of patents, the TRIPS Agreement, and the health law and its derivative regulations, especially the doctrine and concept of LWR, the balancing right and obligations of both patent ownership, the principle of flexibility associated with policy import and supply of pharmaceutical products in Indonesia.

In particular, LWR in this study is analyzed from the dynamics of the Indonesian Patent Law system, which has undergone several changes. This study focuses on the regulation of patents contained in several national policies, namely the Patent Law No. 6 of 1989, the Patent Law No. 13 of 1997, the Patent Law No. 14 of 2001, the Patent Law No. 13 of 2016, and Article 107 of Law No. 11 of 2020 concerning job creation. LWR was first regulated in the patent legal system in Indonesia in the Patent Law No. 6 of 1989, namely in Articles 17, 18, and 20. Article 18 reads that the owner or holder of a patent has special rights to exercise his patent in a company, either individually or jointly. themselves or by giving consent to others, to make, sell, rent, deliver, use, provide for sale or rent or deliver the results of the patented product, and the holder is also entitled to use the patented production process to make goods. Article 18 states that the patent holder is obligated to apply for the patent in Indonesia, and Article 20 expressly states that the import of production products for which a patent is granted or is carried out using a process for which a patent is granted does not constitute the implementation of a patent (Roisah, 2017).

The theory used in this study is about the legal politics of patents, which focuses on the national interest to pursue local production of patented inventions. This is motivated by the fact that in some of these changes, legal politics has also experienced dynamics. As the main theoretical focus, legal politics is operationally defined as a tool or as a means and steps that can be used by the government to create a national legal system to achieve the ideals of the nation and the goals of the state (Sunaryati, 1988). Law is broadly defined as a tool to achieve goals and achieve goals, and legal politics is defined as the direction that must be

taken in law making and enforcement in order to achieve the ideals and goals of the nation in other words legal politics is an effort to make the law a process of achieving goals (Mahfud, 2006). Thus, national legal politics must be directed at the ideals and goals of the nation as stated in the Indonesian Constitution (Assalmani, 2021), to create a just and prosperous society based on *Pancasila*¹ by protecting all Indonesians, promoting the general welfare, educating the nation's life and carry out world order based on freedom, eternal peace, and social justice.

4. RESULTS: GOVERNANCE IN LWR SETTINGS IN INDONESIA

LWR is also linked to the mandatory license in Article 82 (para. 2) of the Patent Law No. 13 of 2016, that for a patent holder who is unable to carry out his invention in the territory of the Republic of Indonesia within 36 months of the patent being granted, any party may submit a request for a Compulsory License to the District Court to implement patent. A patent right is null and void if, within 48 months of the patent being granted, an invention cannot be carried out by the patent holder (Article 94). The birth of the LWR provisions in the Patent Law No. 6 of 1989 was inseparable from the situation of community resistance at that time; this was related to changes in intellectual property rights (IPR) regulations (Budi, 2019; Masnun & Roszana, 2019). The implementation of patents can basically be done by direct investment, patent licenses, or "joint-production" contracts.

The legal politics of patent policy is in line with Sunaryati's (1988) thought that the protection of patent rights includes individual rights and community rights. Individual rights are reflected as the exclusive property rights of the patent holder and the public's right to obtain and access the technological invention. This is where a principle is needed that aims to balance the interests of the individual owners or rights holders and the interests of the community (Roisah, 2017). Furthermore, it is said that any rights recognized by law, which are granted to individuals, partnerships, or entities, should not be solely for their benefit but the benefit of the whole community. Thus, any rights granted by law, granted to individuals or associations, or other entities are also for the benefit of the whole community (Roisah, Utama, Saraswati, & Whidari, 2018; Sunaryati, 1988).

The adjustment to the provisions of the TRIPS Agreement became the main reason for the amendment of the Law. This is partly seen in the material on the period of protection, exclusive rights, which also include the right to import, the abolition of provisions that state the discovery of food, provisions for drinks and new varieties of plants and animals as discoveries that are not can be patented is abolished, and also the burden of proof is reversed for the violator (Aulia, 2015). The change is at the same time an adjustment to the norms of global economic liberalization and a consequence of Indonesia's participation in the WTO that is also attended by more than 150 countries in the world (Roisah, 2017). This adjustment also illustrates that legal politics further strengthens patent protection that is not balanced by the obligations of patent holders.

¹ *Pancasila* is the official, foundational philosophical theory of Indonesia.

Patents undeniably have a big role in the process of technology transfer and patents are also a strong influence on the development of science and technology, especially in this case, patents are able to encourage research and development by making technology information available in patent documents. Patents are a catalyst for new technologies and thus, business collects and uses patents in the context of licensing, joint ventures and other transactions that generate profits (Idham, 2017; Idris, 2000). The legal politics of LWR is also in the context of creating conditions for increasing the absorption of foreign investment. The assumption is that the guaranteed protection of technology (patent protection) brought into the country will make investors feel safe with the investments they develop (Roisah, 2015).

Adopting or implementing the provisions of the TRIPS Agreement by state parties is a non-negotiable obligation because the TRIPS Agreement applies the principle of full compliance for the parties, which means that state parties have an obligation to comply with the entire contents of the TRIPS Agreement. The tendency to adopt the provisions of international law into national law is something that cannot be denied in the current era of globalization. The interdependence between countries in the world is getting stronger, not even a single country in this world can escape from interdependence with other countries. Dependence does not only concern economic, technological and political issues. There is also a close interdependence between national law and international law (Atmaja, Santoso, & Irawati, 2021; Rahmah, Barizah, & Satria, 2012).

Pharmaceutical products are part of government policies in the health sector, especially regarding the availability of drugs. The policy aims to increase the availability of equity, and independence, ensure the safety and affordability of drugs and vaccines, as well as increase the independence and use of domestic pharmaceutical products and medical devices. This policy is in line with the LWR as specified in Article 20 of the Patent Law No.13 of 2016, especially in the field of pharmaceutical patents. It was enacted to support the policy on the availability of medicinal raw materials, more affordable patent drugs, and more qualified and efficacious drugs. It is also to develop the pharmaceutical industry as transfer innovative drug technology, investing, and supporting the independent use of domestically produced drugs (Roisah, 2018; Roisah & Raharningtyas, 2019).

The drug availability policy is carried out through policies at the upstream (sufficient drug production) and downstream (drug availability in the market). In policies at the upstream level, the initial step taken is to regulate the National Drug Policy based on the Instructions of the Ministry of Health No. 189 of 2006, the preparation of a road map for the development of the drug raw materials (BBO) and traditional medicines raw materials (BBOT) industry through the Regulation of the Minister of Health of the Republic of Indonesia No. 87 and 88 of 2013. Furthermore, with the issuance of the Presidential Instruction of the Republic of Indonesia No. 6 of 2016 concerning the acceleration of the development of the pharmaceutical and medical devices industry, an action plan for the development of the

pharmaceutical and medical devices industry was made through the Regulation of the Minister of Health of the Republic of Indonesia No. 17 of 2017. This action in which the development of the pharmaceutical industry is carried out in stages in four main pillars for the development of raw materials for pharmaceutical preparations in the fields of natural, chemical (biopharmaceutical and vaccine) raw materials.

In fact, the concentration of pharmaceutical companies is still in the downstream sector by producing chemical finished products reaching 92.1%. Meanwhile, the upstream sector (companies that produce medicinal raw materials) is still below 4% (Christianingrum & Mujiburrahman, 2021). Consequently, the need for medicinal raw materials is highly dependent on imports, due to limited production in the country. Imports of Indonesian medicinal raw materials reached 95%. This condition is caused by the technological capabilities of the pharmaceutical industry in Indonesia, in this case, most of them are still limited to drug formulations, namely developing the final product by relying on its superiority or equivalence in bioavailability/bioequivalent (BA/BE) to comparator products (Ariana, 2015). Several new pharmaceutical companies are able to produce several segments of pharmaceutical products that can generally be found in Indonesia, including over-the-counter medicine (OTC), patented, and generics medicine (branded and unbranded). Based on the Healthcare Indonesia Outlook (as cited in Lathifah, 2020), the distribution segment of drugs is 42% generic drugs, 40% OTC drugs, and patent drugs.

The Indonesian pharmaceutical industry has not yet been able to achieve the discovery of new drugs because there are still many obstacles, especially from the investment aspect, because to find a new drug (new chemical entity, NCE, and sell it in the market it costs US\$350-800 million. The development of medicinal raw materials in Indonesia is mainly constrained by technology and human resource capabilities. The independence of medicinal raw materials is currently still very difficult to implement in Indonesia, because there are still very few medicinal raw materials, especially synthetic products (derived from chemicals) produced in Indonesia, given the lack of support from the upstream chemical industry. A bigger opportunity lies in the development of biotechnology-based medicinal raw materials, by utilizing Indonesia's rich biodiversity, which is a potential resource in the pharmaceutical sector. The biodiversity of plants, microorganisms, and marine biota is directly correlated with chemical diversity that has enormous potential for drug development (Ministry of Industry of the Republic of Indonesia, 2021).

However, through the Presidential Instruction No. 6 of 2016 concerning the Acceleration of the Development of the pharmaceutical industry and medical devices, the pharmaceutical industry shows that there is growth, namely until 2019, 53 raw materials have been developed consisting of 1 type of biotechnology product, 1 type of vaccine product, 39 types of natural products, and 12 types of chemical drug raw material products. In 2020-2021, it is planned to develop 34 raw materials consisting of 6 types of biopharmaceuticals, 3 types of vaccines, 13 types of natural, and 12 types of active

chemical or active pharmaceutical ingredients (API). In 2022–2025, it is planned to develop 47 raw materials consisting of 4 types of biopharmaceuticals, 10 types of vaccines, 17 types of natural, and 16 types of chemicals (Setditjen Farmalkes, 2021). In addition, the government's policy of providing access and promotion of generic drugs more than providing access to innovative/patented drugs in Indonesia is due not only to the price of innovative/patented drugs being much more expensive than generic drugs but because of the growing domestic pharmaceutical industry related to patent drugs/innovative drugs is still limited. The government's policy is to limit/restrict imported medicinal products, including patented/innovative drugs (drugs that are still under patent protection) which are mostly produced by foreign pharmaceutical companies by requiring the registration of imported drugs to go through the domestic pharmaceutical industry. A comparison of drugs and generic drugs can be seen in BPOM (2020) that in the last 4 years 429 new drugs and 3560 registered generic drugs or 1:12, or patent drugs circulating in the market 12% of all drugs in circulation. This means that the availability of innovative/patented drugs available on the market and accessible to the public is 12% of the total number of drugs on the market. The number of registered innovative drugs/patents is compared with the number of active compound drug patents and pharmaceutical patents granted in the Directorate General of Intellectual Property Database, 1141 and 360 patents, so not all pharmaceutical patents and active compound drugs are registered or circulated in the pharmaceutical product market in Indonesia (BPOM, 2020).

The amendment to Article 20 of the Patent Law No. 13 of 2016 by replacing importation to abort the obligation to implement domestic patents (LWR) in addition to making the rights and obligations of pharmaceutical patent owners less balanced, but also not in line with the policy and legal politics of the supply and development of medicinal pharmaceutical products. This is the same as mitigating or marginalizing the main mission of the accessibility policy on the availability, and affordability of drugs, and independence in using domestically produced drugs. Besides that, importation can hinder the development of medicinal raw materials and the independence of using domestically produced drugs. Indonesia as a country rich in bio-diversity and supported by the culture of the people consuming herbal medicine has the potential to develop drug/vaccine raw materials that lead to biopharmaceuticals. Besides, there needs to be a mandatory assignment policy for state-owned pharmaceutical companies to conduct research in collaboration with academics at universities with pharmaceutical industry players to produce inventions of medicinal raw materials or active drug compounds to reduce imports of medicinal raw materials.

5. DISCUSSION: INTEGRATED POLICY IN HARMONIZING LWR PROVISIONS IN INDONESIA

The patent in Indonesia is regulated in the Patent Law No. 6 of 1989. One of the main considerations for the birth of this patent law is as a requirement for the protection of intellectual property rights for

technology brought in by foreign investors. The explanation of the patent law stated its objectives as the steps to create passion and enthusiasm for technological inventions are very important (Roisah, 2018). At least the climate will allow the Indonesian people to know and improve their capabilities and master technology. Regarding LWR, the strengthening of the legal politics of the LWR policy is also seen in the provision of sanctions, the threat of patent abolition if the patent holder does not implement LWR or when the implementation of the compulsory license is unable to prevent the implementation of LWR from harming the interests of the wider community. Elucidation of Article 132, para. (1), letter d of the Law No. 16 of 2016 stated that harming the interests of the community is meant that even though a compulsory license has been granted, the granting of a compulsory license is not followed by its implementation. In other words, a compulsory license is implemented but it is not effective. The product that is very much needed by the community is not fulfilled and the purpose of granting the compulsory license is not carried out. For example, the granting of a compulsory license to produce drugs is not implemented effectively so that the quantity produced remains small and the price of the drug remains high.

To strengthen the ability to face global competition, Indonesia realizes that technology has a role in answering the nation's development problems and increasing economic growth. Through the absorption of investment and providing employment, technology needs to be a major concern. In addition, an integrated and harmonized economic policy and technology policy are needed to increase national competitiveness. LWR provisions need to be harmonized and integrated with other policies outside of intellectual property rights law policies, such as policies on technology transfer, industrial development, trade, and investment (Roisah, 2017; Roisah & Raharningtyas, 2019). The legal politics of LWR in the context of protecting the public interest is contained in the provisions of Article 82, that the implementation of LWR, whether carried out by the owner/patent holder or through the license holder, can be applied for a compulsory license without being limited in time or at any time as long as the patent protection period is deemed detrimental to the public interest. Provisions relating to the failure of LWR not being implemented within 36 months may allow the mandatory license to be maintained. A delay in the implementation of LWR exceeding 36 months (maximum 12 months) can be requested with reasons and accompanied by written evidence (Figure 1).

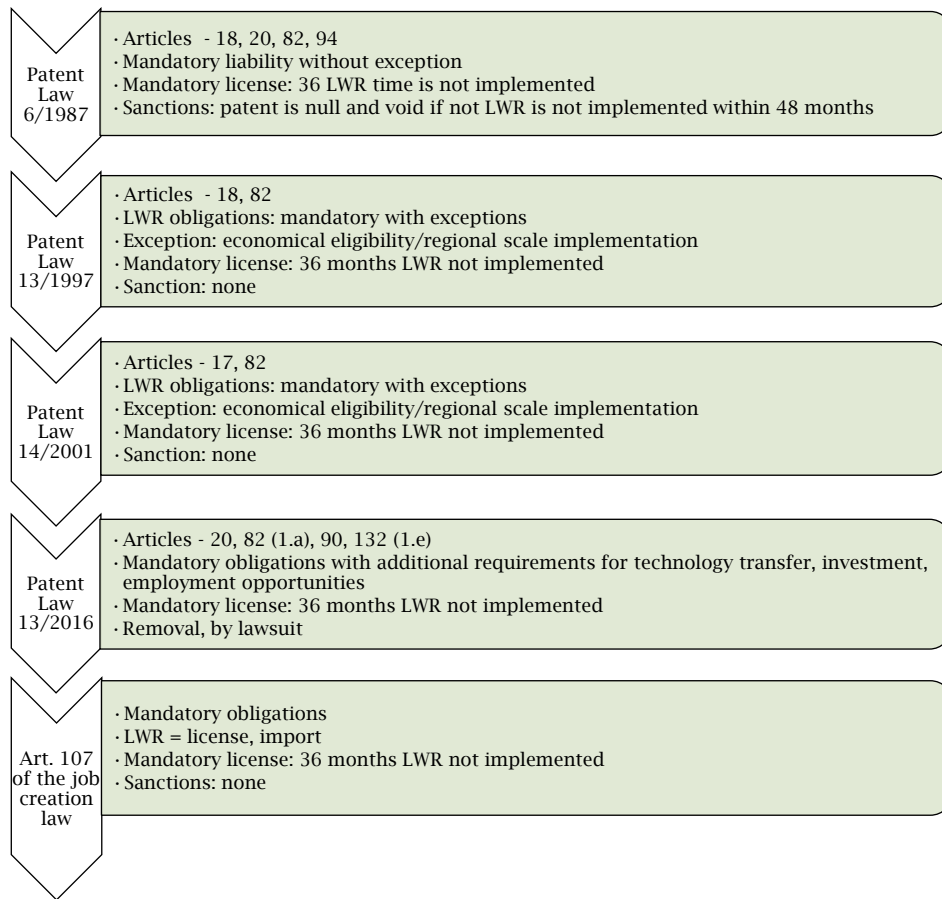
The new provisions regarding mandatory licensing in the Patent Law No. 13 of 2016 related to pharmaceutical patent products are the implementation of the 2003 Doha Declaration and Protocol Amendment Article 31 of TRIPS Agreement 2005. Provisions on the possibility of granting a compulsory license for the import of pharmaceutical products that are patented in Indonesia but cannot be produced in Indonesia for the treatment of diseases in humans. Provisions on the possibility of granting a compulsory License to export pharmaceutical products that are patented and produced in Indonesia for the treatment of diseases in humans based on requests from developing or

undeveloped countries. The strengthening of legal politics has caused discomfort for patent holders, especially foreign patent holders. The discomfort has occurred since the 2016 Patent Bill was discussed in the House of Representatives. The LWR regulation in the Patent Law No. 13 of 2016 was later amended through Article 107 of Law No. 11 of 2020 on job creation by changing the elimination of requirements for technology transfer, investment absorption, and job creation. Besides that, it also adds provisions that are categorized as LWR, namely importing or carrying out product or process patent licenses.

In the midst of the pros and cons of the provisions of Article 20 of the Patent Law No. 13 of 2016, the government issued the Minister of Law and Human Rights Regulation No. 15 of 2018 concerning the implementation of patents by patent holders, as the implementing regulation of Article 20 of the Patent Law No. 13 of 2016. The obligation to

manufacture products or use processes in Indonesia is the same as Article 20 of the Patent Law No. 13 of 2016. The delay in the implementation of the manufacture of products or processes for a maximum of 5 years by applying to the Minister is accompanied by reasons — application for postponement of implementation no later than 3 years from the date of granting the patent. The postponement of the implementation of the patent may be extended along with the reasons. Firstly, the regulation of the Minister of Law and Human Rights No. 15 of 2018 seems to negate the spirit that has been regulated in Article 20 of the Patent Law No. 13 of 2016. Secondly, there is no legal certainty regarding the limit of delays in not carrying out the obligations of the patent holder. Thirdly, implicitly the formulation of the provisions is more pro to foreign interests than domestic interests (Masnun & Roszana, 2019).

Figure 1. Conceptual arrangement of LWR governance in Indonesia



The reason that Article 20 contradicts Article 27 of the TRIPS Agreement is that it is considered discriminatory and is something that is forced. Article 27 of the TRIPS Agreement clearly cannot be read alone. It must be read systematically in the unity of the idea with the other articles. Firstly, the TRIPS Agreement highly respects the rule of law of the participating countries. Secondly, the TRIPS Agreement respects the national interests of participating countries. Thirdly, the TRIPS Agreement still wants the monopoly right to have a good social impact by preventing abuse of

intellectual property rights by right holders in the form of blocking patents and failure to work as adopted from Article 5A of the Paris Convention.

The conflicting provisions of the LWR are based on Article 5A of the Paris Convention of the TRIPS Agreement based on the source of reference and based on the interpretation of the text and context of the destination of Trips (in accordance with the 1969 Vienna Convention on Law Agreement) most states there is no conflict. Historically, there has been no decision from the Dispute Settlement Body stating that there is a conflict between LWR

and Article 27, para. 1 of the TRIPS Agreement. The LWR provisions are in line with the objectives and principles of the TRIPS Agreement as contained in Articles 7 and 8, namely a balance between the rights and obligations of the patent holder for the promotion and contribution of innovation, technology transfer, for social and economic welfare, protection of public health and public interest, and to prevent the misuse of intellectual property rights.

6. CONCLUSION

The results showed that the legal politics of the need for amendment of Article 20 of the Patent Law No. 13 of 2016 is more about adjustments to the provisions of the TRIPS Agreement. As the Patent Law does not discriminate whether the provision is aimed at patents for mechanical, computer, or pharmaceutical products, this needs attention because the policies and benefits of patents between pharmaceutical and non-pharmaceutical products are very different. Therefore, the provisions need to be amended by taking into account the regulatory implementation of pharmaceutical and non-pharmaceutical patents. Amendments to the provisions still need to harmonize with the international regulatory system, but still, strive to support and encourage the independence and capability of the national industry.

Specifically related to the pharmaceutical industry, the benefits of patents themselves must provide great benefits for the community related to access to services/availability of drugs, while taking into account the needs of the community, scientific development, and national capacity in providing cheap and affordable drugs for the community. This condition is illustrated by the placement of the pharmaceutical industry as one of the national priority industries. LWR is a legal instrument that is categorized as a “policy ground”. It is a policy instrument for normalizing the concept of a balance

between rights and obligations. Indonesia as a sovereign country that has a national interest in developing its technology must be expressed in a strategic policy format in its laws and regulations. The enactment policy level is regulated through organic regulations, not at the statutory level. If the regulations are not economically feasible, then exceptions or dispensations and other operational discretionary instruments are made. The point is that the LWR concept is a balance of rights and obligations of patent holders that needs to be pondered, and to get its depth value that granting monopoly rights through patents without being balanced with a transfer of technology and local working will have an impact on the abuse of patents in the form of patent blocking, namely patent registration whose purpose is only to prevent other people from trading in products whose technology is being protected.

The limitation of this research is that it only focuses on the dynamics of the legal politics of the obligation to implement a patent or LWR associated with the principle of flexibility in the provisions of the TRIPS Agreement. LWR is also still limited to the policy of supplying pharmaceutical products and the implications of changing Article 20 of the Patent Law through the Employment Copyright Act (Omnibus Law) by equating or replacing importation as an obligation to implement patents on the policy of supplying pharmaceutical products. Future studies are expected to focus on the application of LWR, knowledge transfer, and technology exchange, as well as the influence of LWR in enhancing the technological capabilities and investments of the grantor of the jurisdiction. In addition, further studies are expected to be able to analyze the level of working requirements in various pharmaceutical fields to determine LWR and as a basis for implementation and legal framework of LWR and importation.

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