Indonesian Patent Policy on Compulsory License and Access to Affordable Medicines

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Abstract

The objective of this research article is to analyze the existence of Indonesian Patent Law and policy on providing a compulsory license to use pharmaceutical patents without consent for patent holders to enhance public health in Indonesia. The focus of this research is to examine whether such law and policy adequate to support access to affordable medicines in Indonesia. The type of this research is normative legal research by using statute and conceptual approaches, while legal resources used in this research is primary and secondary legal resources. The statute approach was used in this research to examine all Indonesia legislation, regulations, and policies dealing with this compulsory license on pharmaceutical patents. This research found that normatively, Indonesian Patent Law and Policy dealing with compulsory license is adequate to secure people's access to affordable medicines. Unfortunately, this compulsory license has not been utilized by the Indonesian Government. The Ministry of Human Rights Regulation No. 39 of 2018 concerning Procedures for Granting of Compulsory License to implement the Patent Act of 2016 has issued to apply for such License. This research advises the Government should ensure that procedure and technical guideline to implement this compulsory license is transparent so that it can be understandable by the third party; thus, accessibility and affordability of medicines can be achieved.

Keywords:*Indonesian Patent Policy, Compulsory License, Access to Medicines*

Introduction

Protection of Intellectual property rights (IPR) in the field of a patent has a significant role in research and development of new medicines and its availability of such medicines on the market to cure many diseases(1). Patent rules are detrimental, not only to the access to medicines, but also medical devices (2). However, such protection also hasa very substantial

effect on public health in many countries(3).The Trade-related Aspects of Intellectual Property Rights (TRIPs) Agreement of 1994, as one of the essential international laws on IPR, recognized that the implementation of this Agreement couldaffectthe price of medicines(4,5).

In Indonesia, for example, initially, patent protection for medicines is expected to provide a beneficial effect on the increase of access to appropriate patented drugs and research and development on health. However, fourteen years ago, the Department of Health has recognized that the TRIPs Agreement has created a significant dependency on developed countries on the stock and availability of medicines (6). This Department of Health argued that patent protection contributes to the unaffordability and inaccessibility of drugs for the people(7). The price of medicine in Indonesia is high compared to international reference prices, and there was a significant difference between the cost of patented drugs and equivalent generic drugs(8). The impact of implementing the TRIPs Agreement in the field of patents on medicines is very much felt by developing countries and raises concerns of the international community(9).

To address the problem, the TRIPs Agreement has provided some flexibility for its Member nations on how to implement such Agreement per country' s national interest on health(3). The Doha Declaration on the TRIPs Agreement and Public Healthis an essential legal instrument to respond to the concern of developing countries on the obstacles they faced when seeking to implement measures to promote access to affordable medicines in the interest of public health (5). One of the legal flexibilities provided by the TRIPs Agreement and the Doha Declaration is a Compulsory License. Article 5 (b) of the Doha Declaration stipulates that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." Although, this Declaration also recognized that members with insufficient or no manufacturing capacities would find difficulties in effectively using Compulsory License.

Based on the above Article 5 (b) of the Doha Declaration and the flexibility provided by the TRIPs Agreement, the Indonesian Patent Act of 2016 includes rule on Compulsory License (10). This research is to analyse the sufficiency of such regulations and policies to enhance access to affordable medicines in Indonesia.

Methodology

This research is normative legal research by using statute and conceptual approaches. Statute approaches are used to analyse the prevailing laws and regulations, both international and

national laws dealing with compulsory license and to find ratio legis behind such laws (11). It usually consists of legal documents made by the authoritative body. At the same time,the conceptual approach is used to analyse the concept of the compulsory license and to develop an argument whether such an idea has been implemented well under the Indonesian Patent Act of 2016. This research uses primary and secondary legal materials. The primarily licensedcontent consists of international laws and national laws, including implementing rules and regulations. While secondary legal materials, is non-legal documents, it derived from books, journal articles, papers, and many others. All the above legal materials then analysed by using both approaches.

Result and Discussion

Concept and Meaning of Compulsory License

Compulsory License is usually known as a non-voluntary licensee, granted by a competent authority like government or court to a third party (a government agency or private party) to use a patented invention without the consent of patent right holder with the payment of reasonable remuneration to the patent right holder(12). One of the rationales for the grant of Compulsory License is to enhance public interest in health, particularly border access to patented inventions, particularly medicines (13). This Compulsory License is provided to address the problem of the high prices of patented drugs,which lead to a public health crisis. Because of that,the Compulsory License is one of the most important legal mechanisms for providing accessibility and affordability of medicines for the people. By granting Compulsory License, the competition between patentee and Compulsory Licensee will reduce price of patented medicines at market.

However, this Compulsory License is not a new concept. This concept emerged in conjunction with the issuance of the first patent law in England, the Statute of Monopoly of 1623(7). The term "Compulsory License" appeared in the Paris Convention for Industrial Property of 1883 (Paris Convention) in its Article 5 (A), which clearly states that "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work" (2). However, Compulsory License shall be refused if the patentee has legitimate reasons to justify his inaction as stipulated under Article 5 (a) (4,14).Under the Paris Convention, the objective of the grant of such a Compulsory License was to settle the problem of insufficient working or

failure to work of a patentand to avoid the abuse of patented invention (15). Such an objective is still relevant until now, although it set up more than a century ago.

Compulsory License under the TRIPs Agreement

In the context of public health, the TRIPs Agreement allows Member nations to adopt measures essential to protect public health and nutrition and avoid the abuse of IP rights (Article 8). One of such measures is "the use of patented inventions without authorization of right holder," or the use of patented inventions by third parties authorized by the government known as Compulsory License as stipulated under its Article 31. Interestingly, the implementation of such a Compulsory License is not limited to least developed or developing countries only, but also for developed countries. Because of that, the majority of the patent law of Member nations provide Compulsory License rules. The purpose of such provisions under the TRIPs Agreement is to provide access to essential medicines in cases of a national public health emergency (16)

The TRIPs Agreement does not restrict the reasons for a Compulsory License. It means that the national law of Members free to determine the cause for the grant of Compulsory License. The application of such reasons under the national law of Members is also different. However, there have been widely accepted reasons for the grant of Compulsory License among Member Nations that are: firstly, the exploitation of patent rights violates competition law. Secondly, patentees abuse exclusive rights by charging high prices of patented medicines. Thirdly, market demand is not satisfied. Fourthly, public is interested in health, environment, and others. Fifthly, dependent patent and lastly, public non-commercial use.

Beforethe Compulsory request license, a third party shall attempt to negotiate a voluntary license with the patent holder (Article 31 (b)). Still, such negotiation is not required in the case of "a national emergency or other circumstances of extreme urgency or cases of public non-commercial use"(17). This exception is restricted to the request of a compulsory license for domestic use only.

Rules of Compulsory License under Indonesian Patent Act

*The Reasons for TheCompulsory License.*The Indonesian Patent Act regulates compulsory license on Articles 81 -107. The Act defined mandatory license is a non-exclusive license issued by Ministerial Decree to use patented inventions based on a request by third parties, for the period less than the period of the patent granted. There are 3 (three) grounds for

compulsory license in Indonesia that are: (a) Patent holders do not make patented products or processes in Indonesia within 3 (three) years after patent being granted; (b) Patents is used by patent holders or licensors in a form that is detrimental to the public interest, and (c) Patent cannot be used without using another party's patent because such patent is the result of improvement of the earlier patent (dependent patent).

The request to use the Compulsory License will be approved if the applicant able to show the evidence of his capacity and facility to use the patent fully and shortly. The applicant also needs to show that measures have been taken to negotiate a voluntary license for a year based on fair terms and conditions, but such an optionalpermit has not been granted. The applicant also needs to show that such a patent can be used in Indonesia in the viable scale of the economy and provides benefits to society. If the request to use a compulsory license is granted, remuneration shall be issued to the patent holder. Such compensation and the method of payment are provided by Ministerial Decree (Article 88).

Per TRIPs Agreement, the Indonesian Patent Act provides a specific rule on semiconductor technology, in which Compulsory Licensee for such technology can use such license for 2 (two) purposes only, that is: (a) non-commercial public interest, and (b) based on court verdict or decision of other agencies which states that the use of such patent is considered as a monopoly or unfair competition (Article 100). Compulsory License is non-transferable, except due to inheritance (Article 102).

The Position of Patent Holder in the Compulsory License.There are several Articles under the Indonesian Patent Act, which specifically mention the position of Patent Holder. Firstly, during the examination process, which patent holder will be called by an expert team to give the arguments or reasons why she or he refuses to grant a voluntary license within 30 days. If the patent holder does not provide evidence within 30 days, she/he is deemed to agree with the grant of compulsory license.

However, the patent holder will receive remuneration from the Compulsory Licensee, in which Ministerial Regulation regulates the amount and method of payment. If the patent holder has objection with the Ministerial Decree due to issuance of a grant of compulsory license, he or she can bring a lawsuit to Commercial Court. The Commercial Court may decide to cancel the Compulsory License. Furthermore, the patent holder receives a copy of the Ministerial Decree for the issuance ofa compulsory license. However, a patent holder is still obligated to pay an annual fee following prevailing regulation.

Interestingly, patent holders could also invoke the cancellation of a compulsory license if: (a) the reasons which formed the basis of the consent no longer exist; (b) the recipient does not use Compulsory License or has not made appropriate preparations to use Compulsory License immediately, or (c). the recipient of the compulsory license does not comply with other terms and conditions like does not provide remuneration or disobey with the scope of License. Based on the above, provisions mean that the position of patent holder is still very influential in the process of granting a compulsory license.

*Purpose and Termination of Granting Compulsory License.*It is important to note that the primary purpose of the issuance of a Compulsory License is to produce patented pharmaceutical products for the treatment of human diseases. However, such production under Compulsory License in Indonesia is not merely to fulfilthe national or domestic need, but also for export and import such products. Compulsory License to the import of patented pharmaceutical products in Indonesia is permitted if such products have not been produced in Indonesia. Otherwise, Compulsory License to export patented pharmaceutical products is allowable if such export is based on the request of developing countries or least developing countries. What is meant by "pharmaceutical products" includes ingredients or tools for diagnosing diseases.

In the context of termination, the Indonesian Patent Act stipulates that Compulsory License terminates due to the completion of the period specified in the Decree to grant such License by the Minister or because commercial court verdict that has permanent legal force annuls the Ministerial Decree concerning the granting of the compulsory license.

Adequacy of Compulsory Licence Rules to Enhance Access to Medicines in Indonesia

Indonesian Government has issued the implementing rules on Compulsory License that is The Ministry of Human Rights Regulation No. 39 of 2018 concerning Procedures for Granting of Compulsory License (18). This Implementing Regulation can be used as a guideline for application and grant of Compulsory License by a third party or by the Government. However, it seems that the administrative procedure of such a claim requires considerable time, and conditions are also not natural to fulfil because strong supporting evidence is needed. This condition may have the potential to inhibit the use of Compulsory License by the third party. In the context of legal drafting, this Ministry Regulation contains several repetitions of the provisions in the patent law.

Before the existence of Patent Act No.13 of 2016, Compulsory License has also stipulated in the Patent Act No 14 of 2001. Although under this Act, such rules are still not as comprehensive as provided in this new Act of 2016. For more than fifteen years, the provisions of Compulsory License under the earlier Act to enhance access to affordable medicines for certain diseases cannot be implemented without the existence of implementing regulation. Accordingly, despite some weaknesses, this Ministry Regulation is vitally important implementing rules so that Compulsory License can be used to support public health, mainly to provide affordability and accessibility of medicines for a certain type of disease in Indonesia to prevent a public health crisis.

Interestingly, under the Patent Act No 13 of 2016, Indonesia can also use Compulsory License not only to fulfila national need on medicines but also for the lack of other least developed or developing countries on patented pharmaceutical products in Indonesia to treat endemic diseases overseas. Indonesia can also import patented pharmaceutical products in Indonesia, but Indonesia cannot still manufacture them. Such provisions constitute a significant development in the area of Compulsory License.

Conclusion

Indonesian Patent Law and its policy have addressed the issue of public health and use the flexibility provided by the TRIPs Agreement and Doha Declaration on Compulsory License to enhance such public health, particularly on providing cheap and affordable medicines to cure some diseases. The Indonesian Patent Law and its policy, together with the Ministry of Human Rights Regulation No 38 of 2018, provide sufficient rules on Compulsory License so that it can be implemented in Indonesia to enhance public health and particularly on access to affordable medicines. Although the administrative procedure may take time, the provision on a Compulsory License is essential in the area of the patent system.

The Government needsto ensure that the procedure and technical guideline to implement this Compulsory License is transparent so that it can be understandable by pharmaceutical companies, third parties. Accordingly, accessibility and affordability of medicines can be achieved.

References

[1] Gold ER et. al. Are Patents Impeding Medical Care and Innovation? PLoS Med. 2010;7(1).

[2] Oguanobi HI. Broadening the Conversation on the TRIPS agreement: Access to Medicines Includes Addressing Access to Medical Devices. J World Intellect Prop. 2018;21(1–2):70–8.

[3] Correa C. Integrating Public Health Concern into Patent Legislation in Developing Countries. Geneva: South Centre; 2000.

[4] Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) of 1994. (Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 15 April 1994, 33 ILM 1197 1201 (entered into force on 1st January 1995).

[5] Doha Wto Ministerial 2001. Ministerial Declaration [Internet]. World Trade Organization. 2001 [cited 2018 Jun 13]. Available from: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

[6] Departemen Kesehatan RI. Kebijakan Obat Nasional. Rancangan. Jakarta: Departemen Kesehatan RI; 2005.

[7] Abbas MZ and SR. Evolution of the Concept of Compulsory Licensing; A Critical Analysis of Key Development Before and After TRIPs. Acad Res Int [Internet]. 2013;4(2). Available from: https://eprints.qut.edu.au/90061/6/90061.pdf

[8] Prahasto ID. Policy Brief, Kebijakan obat Indonesia yang masih belum memihak pasien: Contoh kasus obat generic. Yogyakarta: Pusat Manajemen Pelayanan Kesehatan Fakultas Kedokteran UGM; 2010.

[9] WHO. Public Health; Innovation and Intellectual Property Rights. Report of. Geneva: WHO Press; 2006.

[10] The Act of the Republic of Indonesia Number 13 of 2016 about Patent (State Gazette of the Republic of Indonesia Number 176 of 2016, Supplementary State Gazette Number 5922).

[11] Marzuki PM. Penelitian Hukum. Kencana Prenada Media Group; 2005.

[12] Durojaye E. Compulsory Licensing And Access To Medicines In Post Doha Era: What Hope For Africa? J Intellect Prop Law. 2011;18.

[13] Abbas ZM. Pros and Cons of Compulsory Licensing: An Analysis of Arguments. Int J Soc Sci Humanit [Internet]. 2013;3(3). Availablefrom: http://www.ijssh.org/papers/239-D00013.pdf

[14] Paris Convention for the Protection of Industrial Property, 21 U.S.T.1583, 828 U.N.T.S. 305, 20 March 1883 (entered into force 26 April or 19 May 1970).

[15] Bond E and KS. Compulsory Licensing, Price Controls, and Access to Patented Foreign Products [Internet]. CES-Ifo Conference on Applied Microeconomics. 2012 [cited 2013 Jan 15]. Available from: http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf

[16] Gratzer D. The WTO's Drug Problem [Internet]. Manhattan Institute For Policy Research. 2003. Available from: http://www.manhattan-institute.org/html/miarticle.htm?id=3276

[17] Halijian D. Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a ViableSolution to the Access Medicine. Brooklyn J Int Law. 2013;38(3):7.

[18] Ministry of Human Rights Regulation No. 39 of 2018 concerning Procedures for Granting of Compulsory License.