COMPULSORY LICENSING FOR ACCESS TO AFFORDABLE ESSENTIAL MEDICINE (HEPATITIS C): AN INDONESIAN PERSPECTIVE*

Zulfa Zahara Imtiyaz
Bachelor Degree in Business Laws (International Program)
Faculty of Law, Airlangga University
Email address: zulfazaharai@gmail.com

Received 14 December 19
Revised 2 December 20
Accepted 9 December 20

Abstract

Hepatitis C is one of viral diseases that requires special medication. As a viral disease, it means that it requires essential medicine for the treatment. In intellectual property, this becomes one of the issues because of the pricing of essential medicine. The inventor(s) finding this drug are entitled to an exclusive right to their invention, i.e. patent. In order to guarantee access to the medicine, it requires the regulations that regulate on how to make the patented medicine become accessible especially for Indonesia as a developing country. The TRIPs Agreement and Indonesian Law regulate this matter of compulsory licensing. Compulsory licensing is the way to make the patented medicine accessible for patients. However, even though Indonesia has implemented it, there remains problems for poor patients, and the regulations concerning compulsory licensing are still lacking in Indonesia. On the other hand, the determination of royalty for the inventor(s) must be proportional.

Keywords: Hepatitis C, Compulsory Licensing, Pricing, Regulation, Royalty

* This article is summarized and rearranged from the research "Compulsory Licensing for Access to Affordable Essential Medicine (Hepatitis C): An Indonesian Perspective", Faculty of Law, Airlangga University, 2019.

1. Introduction

With the rising number of years, the more rapid progress of science and technology. It brings a great influence on human life, especially in the pharmaceutical and public health sectors. Also along with the increase of the population from year to year in the world as well as in Indonesia, there is greater potential for disease that can be suffered by society. With the various types of diseases, there are also many kinds of medicines needed. Thus, the human with their creativity invents various types of drugs or medicines. The recognition of findings and creations by an individual has given rise to Intellectual Property Rights.[1]

According to Black's Law Dictionary Intellectual Property (IP) is (a) category of intangible rights protecting commercially valuable products of the human intellect. It comprises primarily trademark, copyright, and patent rights, as well as trade-secret rights, publicity rights, moral rights, and rights against unfair competition. According to the World Intellectual Property Organization, IP refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names, and images used in commerce. It is divided into two categories:

1. Industrial Property includes patents for inventions, trademarks, industrial designs, and geographical indications.

2. Copyright covers literary works (such as novels, poems, and plays), films, music, artistic works (e.g., drawings, paintings, photographs, and sculptures) and architectural design. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and broadcasters in their radio and television programs.[2]

---

[1] Sartika Nanda Lestari, 'Implementasi Compulsory Licensing Terhadap Obat-Obatan dalam Bidang Farmasi di Indonesia' (Studi Berdasarkan Doha Declaration on the TRIPS Agreement and Public Health) (Thesis, Master Program on Jurisprudence Diponegoro University, Semarang 2012) 17.

[2] World Intellectual Property Organization, 'What is Intellectual Property' <www.wipo.int,> accessed 4 September 2019.

Indonesia, as a developing country has many types of diseases, even fatal diseases. In 2013 the prevalence of hepatitis C in Indonesia increased among children at the age of 15 years or below. One type of hepatitis that infects the population of Indonesia is Hepatitis C (2.5%).[3] Hepatitis C is a liver disease caused by the hepatitis C virus (HCV): the virus could resulted in both acute and chronic hepatitis, ranging in severity from a mild illness lasting a few weeks to a serious, lifelong one.[4] Hepatitis C virus infection is a global health problem and is the main cause of chronic liver disease worldwide.[5] Globally, approximately 71 million people have chronic hepatitis C virus infection. WHO estimated that in 2016, approximately 399,000 people died from hepatitis C, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer).[6] In Indonesia, viral hepatitis is a significant public health problem. Currently, around 2.5 million are infected with HCV.[7] The national prevalence of HCV has remained stable and predicted to remain at its current level without focused intervention.[8] Since hepatitis C remains one of the health problems in developing country especially Indonesia, Indonesia needs to facilitate access to those medicines. However, the problem is their high prices that cause them inaccessible.

---

[3] Kementerian dan Kesehatan Republik Indonesia, 'Situasi Penyakit Hepatitis B di Indonesia Tahun 2017' *Infodatin (Pusat Data dan Informasi Kementerian Kesehatan RI,* 2017) 2.

[4] World Health Organization, 'Hepatitis C' <www.who.int> accessed 5 September 2019.

[5] Muhammad Umar, *et al,* 'Diagnosis, Management, and Prevention of Hepatitis C in Pakistan 2017' (2016) 28(4) Journal of Ayub Medical College Abbottabad-Pakistan 839.

[6] World Health Organization (n 4).

[7] Jonathan Scrutton, Jack Wallace, and Suzanne Wait, 'Situation Analysis of Viral Hepatitis in Indonesia: A Policy Report' (*Coalition to Eradicate Viral Hepatitis in Asia Pasific,* July 2018) 12.

[8] ibid, cited from Sibley A, Han KH, Abourached A, et al. 2015, 'The present and future disease burden of hepatitis C virus infections with today's treatment paradigm' Vol 3 J Viral Hepat 22 Suppl 4, 21-41.

The access to medicines strongly relies on pricing and financing mechanisms that can be differently applied to each country. In developing countries, in the absence of broad health coverage systems, a large part of expenditure comes from patients' own pocket, provided, of course, that their level of income allows them to afford it. This does not happen, however, in many cases where medicine prices are inaccessible to various segments of the population. As medicines are financed by a third-party payer, high prices are the biggest source of pressure on the budget.[9] This pricing issue is due to the patent right of a patent holder. The notion of Intellectual Property Rights is based on the principle that the person who made an intellectual contribution must have an exclusive right to enjoy the fruits of his labor.[10] As a result, the monopoly practice might happen because of the principle of this exclusive right that the patent holder could use the right within a certain period of time. This exclusive right gives a patent holder the right to monopolize through pricing and medication restriction. The practice of monopoly rights makes the developing countries such as Indonesia unable to access essential medicines. Indonesia is one of the countries that urges the application of certain policies on the use of patents on essential drugs (self-producing patented medicines) to reduce the cost of essential medicines for which the patents have been registered.[11] Self-producing patented medicines means to produce generic

[9] Carlos M. Correa and German Velasquez, 'Access to Medicines: Experiences with Compulsory Licenses and Government Use – The Case of Hepatitis C' (2019) South Centre Research Paper 85, 1.

[10] Muhammad Zaheer Abbas and Shamreeza Riaz, 'Evolution of the Concept of Compulsory Licensing: A Critical Analysis of Key Developments before and after TRIPS' (2013) 4(2) Journal Savap Academic Research International, 482.

[11] Sartika Nanda Lestari (n 1) 28.

version of certain drugs that are still protected by patent, either through compulsory licensing or government use.[12]

This situation could lead to non-accessible drugs for poor patients. According to Article 28H paragraph (1) of the 1945 Constitution, which stipulated that *"Each person has a right to a life of well-being in body and mind, to a place to dwell, to enjoy a good and healthy environment, and to receive medical care."* Based on this stipulation, it is clear that everyone has the right to a life of well-being in body and the right to receive medical care. Related to the health policy in Indonesia, as one of the examples of developing countries, health is one of the eleven priorities in the national development program. It is stipulated in the Regulation of the President of the Republic of Indonesia Number 5 of 2010 on the National Medium-Term Development Plant (RPJMN) 2010-2015. Furthermore, the right to health is also recognized as human right based on the Act Number 36 Year 2009 regarding Health. Article 5(1) of the Act number 36 Year 2009 states: "Every people shall have equal right in obtaining access to health resources". It has been stipulated also in Article 16 of the Act Number 36 Year 2009 that the Government shall be responsible for the availability of fair and proportional distributed resources of health for all people in order to achieve maximum health degree.[13] Thus, Indonesia must make drugs for viral disease affordable, especially where the country does not yet have local or insufficient manufacturing in the pharmaceutical sector for making these drugs. Therefore, the DOHA Declaration on the TRIPS Agreement and Public Health, which was enacted in 2001, becomes relevant.

The WTO Director General's speech conveyed that each WTO member country has the right to regulate flexibility over drug patents. This

[12] Tomi Suryo Utomo, 'Implikasi Pasal-Pasal Pelindung (The TRIPS Safeguards) Dalam UU Paten Indonesia: Kritik, Evaluasi, dan Saran Dari Perspektif Akses Terhadap Obat Yang Murah dan Terjangkau' (2007) 14(2) Jurnal Hukum, 272.

[13] Sri Wartini, 'The Legal Implication of Compulsory License Pharmaceutical Products in the TRIPs Agreement to the Protection of the Right to Health in Developing Countries' (2018) 18(1) Jurnal Dinamika Hukum, 5.

flexibility is called compulsory licensing, which is expected to be able to answer problems faced by countries that could not afford to buy patented drugs or do not have capabilities and are less able to produce drugs on a local scale.[14] According to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, where it is stated that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement" it could be said that compulsory licensing is a form of freedom/rights given to developing countries for making, accessing or selling drugs "second class" for drugs that have been patented with the aim of public health.[15] Under Article 31 on Other Use Without Authorization of The Right Holder of the TRIPs Agreement, Section 5 on Patent, there are four requirements for granting a compulsory license which are, as follows:

a. Emergency and extreme urgency;
b. Anti-competitive practice;
c. Public non-commercial use;
d. Dependent patents.

The regulation makes the situation for Indonesia as one of the developing countries more flexible in accessing the essential drugs for hepatitis C disease and could increase people's welfare. Thus, Indonesia implements this by passing a regulation which is Government Regulation Number 39 of 2018 on Procedure for Granting a Compulsory License. However, this is quite challenging for the Indonesian Government as well. This research would discuss the issue that high pricing remains a problem despite the Government's effort to implement the compulsory license policy, mainly because of the lack of regulations concerning the compulsory license in Indonesia; and the royalty determination issue.

[14] Samariadi, 'Pelaksanaan Compulsory Licensing Paten Obat-Obatan Bidang Farmasi di Indonesia Dikaitkan Dengan *DOHA Declaration on the TRIPS Agreement and Public Health'* (2016) 1(2) *De Lega Lata*, 451.
[15] ibid.

2. Pricing Issue of HCV Medicine in Indonesia

A compulsory license can be issued by a government to allow a local company to manufacture the patented product or to import it under certain conditions.[16] Article 31(f) of the TRIPS Agreement stated that "*any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.*" However, a mechanism put in place in 2003 allows WTO members to waive this condition to grant special compulsory licenses for the manufacture and export of generic medicines to countries that do not have local manufacturing capacities in order to supply the needed medicines to their patients.[17] However, unlike Malaysia which imported generic versions of the drugs from India, Indonesia used the compulsory license to appoint local manufacturers to produce 7 medicines for treating Hepatitis B and HIV/AIDS based on Decree of the President Republic of Indonesia No. 76 of 2012.[18] This also happens in the case of hepatitis C medicine.

Historically, Indonesia's pharmaceutical drug utilization has been the lowest in the region compared to neighboring markets; however, with its trend of significant and sustained population growth, the country is seeing increasing demand for access to safe, effective medications and healthcare services. In particular, Indonesia's changing epidemiology of chronic illnesses such as diabetes, obesity, cardiovascular diseases, and other similar conditions has revealed a rise in related incidence as well as unprecedented healthcare needs.[19] This includes hepatitis C disease. In this situation, Indonesia has improved in several ways. The recent investment in manufacturing facilities comes amid an expected rise in demand for

[16] World Health Organization, 'Global Report on Access to Hepatitis C Treatment' (*WHO*) <www.who.int,> accessed 28 October 2019, 26.

[17] ibid; *see* http://www.who.int/phi/promoting_access_medical_innovation/en.

[18] Sri Wartini (n 13) 7.

[19] Global Business Guide Indonesia, 'Indonesia's Pharmaceutical Industry is in Rude Health' (*Global Business Guide Indonesia*) <www.gbgindonesia.com> accessed 28 October 2019.

domestically made generic drugs, driven by government efforts to expand national health insurance offerings.[20] In 2014 officials launched the Jaminan Kesehatan Nasional scheme, which aims to provide universal health coverage to Indonesian citizens by 2019. Given the significant expansion of services required to meet this objective, the use of unbranded or generic medicines has been encouraged in order to reduce costs.[21]

The existence of compulsory licensing on hepatitis C medicine is a tool for accessibility. Now, there is DAA (Direct Acting-Antiviral) medicine which is generic medicine of hepatitis C with *sofosbuvir*[22] type. The distribution permit of this medicine has been approved by BPOM (National Agency of Drug and Food Control). The producers of this generic medicine are PT. Soho Indonesia and PT. Kimia Farma. The *sofosbuvir* tablet approved by the BPOM is a product with the trade name Sovaldi (registrant PT. Soho Indonesia, approved June 30, 2016). Also PT. Kimia Farma as the registrant for the *sofosbuvir* with the trade name Myhep (approved July 1, 2016).[23]

Pricing issues were the most important problem for compulsory licensing in Indonesia. Despite the fact that Indonesia has applied compulsory license for DAA or generic version of hepatitis C medicine, the access to DAA remains limited because pharmaceutical companies set prices that are not affordable. *Sofosbuvir* price in Indonesia is 10 times more expensive than that in India. This is proven by data in September 2017 when *sofosbuvir's* price in India was only $14 or around 200,000 ruphias,

---

[20] Oxford Business Group, 'Indonesia Bolsters Domestic Pharmaceuticals Production Capacity' (*Oxford Business Group*) <www.oxfordbusinessgroup.com> accessed 9 November 2019.

[21] ibid.

[22] According to Indonesia National Agency of Drug and Food Control, Sofosbuvir is a nucleotide prodrug that will undergo intracellular metabolism into an active form of uridine triphosphate analogue, which is a non-structural (NS) 5B Ribonucleic Acid (RNA) polymerase inhibitor of Hepatitis C virus (HCV).

[23] Badan POM, 'Badan POM Menyetujui Izin Edar Sofosbuvir, Obat Hepatitis C' <www.pom.go.id,> accessed 20 November 2019.

while in Indonesia the price was around 2,200,000 ruphias.[24] This could lead to the crisis of scarcity of hepatitis C medicine due to the monopoly practice conducted by pharmaceutical companies, as Indonesia only has two pharmaceutical companies in the market.

To solve the problem mentioned above, *first,* Indonesia must encourage the research and development (R&D) investments that can produce new drugs especially ones on hepatitis C disease by enlarging the incentive scheme. Based on data in 2019, in Indonesia 95% of drug raw materials remains dependent on imports.[25] As such, with R&D investments, Indonesia would no longer rely on compulsory licensing of hepatitis C medicine. *Second,* the R&D to find a new medicine must be associated with encouraging local production which is a long-term sustainable development. Lower prices can also be achieved by supporting local production of drugs through voluntary licensing and technology transfer. The authorization of technology through technology transfer is much cheaper than buying new technology.[26] Technology transfer is the implementation of developing countries' rights to obtain technology from developed countries. This could be seen in Declaration on the Progressive Development of Principles of Public International Law Relating to A New International Economic Order.[27] In its process, there are parties involved, which are, the owner of technology as the party providing the technology, the State that owns the technology,

[24] Whisnu Bagus Prasetyo, 'Obat Hepatitis C di Indonesia Lebih Mahal 10 Kali Lipat Dibanding India' (*Berita Satu*, 29 July 2018) <https://www.beritasatu.com/nasional/503222/obat-hepatitis-c-di-indonesia-lebih-mahal-10-kali-lipat-dibanding-india> accessed 21 November 2019.

[25] Dewi Rachmat Kusuma, 'Jokowi: 95 Persen Bahan Baku Obat Masih Tergantung Impor' (*Kumparan Bisnis*, 21 November 2019) <https://kumparan.com/kumparanbisnis/jokowi-95-persen-bahan-baku-obat-masih-tergantung-impor-1sIR5Ov5VZt> accessed 21 November 2019.

[26] Slamet Yuswanto, 'Upaya Mewujudkan Alih Teknologi Melalui Waralaba' (2019) 4(1) UBELAJ, 73.

[27] ibid.

the technology recipient as the party as well as the State receiving the technology.[28] This is a long-term, sustainable strategy that has the added benefits of stimulating the economic development and enhancing autonomy of developing countries.[29] Industrialized countries should extend technology transfer as well to countries that already have some manufacturing capacity, as these will be the best candidates to start manufacturing drugs that are out of reach mainly because of price.[30] These solutions can also benefit developing countries that could become regional suppliers and could make the price of hepatitis C medicine more affordable for patients.

3. Implementation of Indonesian Compulsory Licensing: Lack of Regulations

One of the legal implications of compulsory licensing is the accessibility and affordability of the essential medicine which are deserved by patients in developing countries, such as *Antiviral* and *Antiretroviral,* since the developing countries can use the justification based on the reason of protecting public health and also the developing countries have a freedom to issue the law to determine what emergency situation to justify the implementation of compulsory license. Thus, the compulsory license enables state to protect the right to health.[31]

The procedure to grant a compulsory license is, however, governed by the respective national (patent) law, which has to define the specific grounds for which a compulsory license can be granted as well as the procedure to be followed.[32] Hence, the Indonesian Government has already

---

[28] ibid, 74.

[29] Ellen 't Hoen and Suerie Moon, 'Equity Pricing of Essential Medicines in Developing Countries'<https://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/15thoen_e.pdf> accessed 23 November 2019.

[30] ibid.

[31] Sri Wartini (n 18) 6.

[32] World Health Organization (n 6).

amended the Patent Act by following the TRIPs Agreement. The reason for exercising compulsory license in Indonesia is based on Article 109 of the Indonesian Patent Act. With the existence of Patent Law specifically concerning compulsory licensing, it is necessary to have further provisions in the form of Government Regulation. However, the lack of regulation of compulsory licensing in Indonesia has become one of the problems in the patent law. Government Regulation concerning compulsory licensing still does not exist. There is only Ministerial Regulation Number 39 of 2018 concerning the Procedures for Granting of Compulsory Licensing.

The regulation came as a surprise for many companies, especially as there was no prior consultation with the private sector in its drafting process. Initial reading shows the regulation needs further clarity in terms of scope, urgency and technical guidelines as some articles contain very general and/or vague provisions related to compulsory licensing implementation.[33] This could be seen in Article 22 of Ministerial Regulation Number 39 of 2018. Article 22 specifically governs the use of compulsory licensing for pharmaceutical products, which states that the Minister of Law and Human Rights may grant compulsory licensing to produce, import and export pharmaceutical products with patents in Indonesia for the purpose of "curing human disease". From that statement, there are no further details in the article on how it will be implemented.[34]

The release of the regulation also potentially contradicts Ministerial Regulation No. 15 of 2018 on the Postponement of Local Manufacturing Requirements, which allows patent holders to delay the implementation of local manufacturing for five years, and can be extended. The release of the compulsory licensing regulation opens up a greater risk for patent holders applying for a postponement that their product will be requested for compulsory licensing.[35] Therefore, in this case, Indonesia needs to enact the

[33] Gilang Ardana, 'Government Releases Compulsory Licensing Regulation' <www.amcham.or.id.> accessed 24 November 2019.

[34] ibid.

[35] ibid.

government regulation specifically concerning compulsory licensing as the implementing regulation of patent law, not only the ministerial regulation. Despite the fact that there are Government Regulation Number 27 of 2004 on Procedures for Patent Exploitation by Government Use and Presidential Decree No. 83 of 2004 on Patent Exploitation by the Government on Anti Retrieval Medicine that the Government has been using those rules in implementing compulsory licensing, it is inadequate and is not well targeted in regulating the compulsory licensing because in essence, compulsory licensing and Patent Exploitation by Government Use are different. Also, specifically, Indonesian Intellectual Property Rights Law has mandated in its Article to regulate further provisions regarding license agreement with government regulation, however, until now the government regulation has not been ratified.[36] This leads to the consequence that Indonesia is still lacking in the regulation of compulsory licensing, which is the government regulation as the implementing regulation to the correspond laws of patent for the parties in the case of compulsory license.

The issue of lacking in regulation for the payment of royalty to the inventor(s) under compulsory licensing is also a problem. Because there is only a regulation concerning royalty on patent exploitation by government use. The royalty regulation concerning compulsory licensing is still missing. From this situation, in order to provide good regulations regarding compulsory licensing, for the sake of prosperous society especially in the health sector which is for hepatitis C patients in Indonesia, the enactment of government regulation concerning compulsory licensing must be done as soon as possible. This also intended to provide legal certainty to the parties in patent activities regarding compulsory licensing, specifically in pharmaceutical sector.

[36] Sulasno, 'Lisensi Hak Kekayaan Intelektual (HKI) Dalam Perspektif Hukum Perjanjian di Indonesia' (2012) 3(2) *Adil Jurnal Hukum,* 357.

4. Determination of Royalty: The Right of Inventor(s) and the Patent Holder(s)

Article 31 letter (h) of TRIPs Agreement stated that "*the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization".* In Indonesian Patent Law, Article 1 number 14 stated that royalty is compensation given for the use of patent rights, which is further explained in Article 1 number 15 about the meaning of compensation itself. Thus, we can conclude that patent royalty is fee granted by the patent applicant to the inventor(s) for the results of their invasion in certain fields of technology, specifically in this case is medicine. Royalty concerning the granting of compulsory license in pharmaceutical products is regulated by Article 92 and Article 93 of Law No. 13 of 2016 on Patent. Further provisions regarding the calculation of royalty on Patent in Indonesia is regulated by Ministerial Regulation No. 72/PMK.02/2015 on Compensation from Non-Tax State Royalty Income to Inventor(s). However, this Ministerial Regulation only applies to royalty payment for the patent by government use. If the patent is not carried out by the government, the procedure for royalty payment shall be determined by an agreement agreed between the inventor and the patent holder. The issue of royalty is also regulated under Government Regulation No. 27 of 2004 on Procedures for Patent Exploitation by Government Use Article 10. However, as it already explained in the previous sub-chapter, this Government Regulation is inadequate and not well targeted in regulating compulsory licensing.

The determination of royalty rates on compulsory licensing is also one of the issues in this case. The question is whether the rate could be classified as an adequate remuneration for the inventor(s) or not. A more important reflection is what adequate remuneration should amount to. Due to the obvious reason that most developing countries lack available funds, which makes them unable to pay even modest royalties without financial assistance and so leaving the flexibility unreachable. The consequence will be the same if royalty rates are set too high. Conversely, low royalty rates

may well lead to an excessive use of compulsory licenses, which in turn, might be perceived by pharmaceutical companies as excluding monopoly profits and putting investments at stake. Hence, the risk in this situation is that compulsory licensing could undermine incentives for R&D investments and slow down the development of new drugs.[37] Thus, the role of the government in making regulation regarding royalties payment of compulsory license, should take into account on how to provide proportional royalties to inventor(s), so that no party feels disadvantaged.

5. Conclusion

Since hepatitis C is one of chronic diseases that could resulted in death and supposedly requires special medication, it causes problems. The first problem is about the pricing of the medicine itself. Indonesia as one of developing countries, usually lacking fund, has to implement compulsory licensing for patent medicine (hepatitis C) in order to improve its citizens' right to health according to the TRIPs Agreement and Indonesian Patent Law. However, it turns out that compulsory licensing is still not the right solution because of the inaccessibility problem, especially for poor patients. Despite the existence of compulsory license that could make the medicine affordable, the costs are still 10 times more expensive than those in India. To solve the problems, Indonesia must make R&D investments, at once, with the incentive scheme that continues to be improved in order to find new drugs for hepatitis C. Transfer of technology is also needed to support this.

The implementation of compulsory license in Indonesia has been running for a long time. Yet, the regulation of compulsory license is still lacking. Indonesia in implementing compulsory licensing is still bound to use the government regulation No. 27 of 2004 on Procedures for Patent

[37] Anna Niesporek, 'Compulsory Licensing of Pharmaceutical Products & Access to Essential Medicines in Developing Countries' (Thesis**,** Linköping University, Sweden 2005) 30.

Exploitation by Government Use where the substance patent exploitation by government use and compulsory license are different. Thus, the government should enact new government regulations focusing specifically on the compulsory license, so that the parties get legal certainty.

The problem of determination of royalty is also important for making regulation that give proportional royalties to the parties, so that no party feels disadvantaged. Thus, the government role is very important in determining royalties for compulsory license scheme.

Bibliography

Journal Articles

Abbas MZ and Riaz S, 'Evolution of the Concept of Compulsory Licensing: A Critical Analysis of Key Developments before and after TRIPS' (2013) 4(2) Journal Savap Academic Research International

Correa CM and Velasquez G, 'Access to Medicines: Experiences with Compulsory Licenses and Government Use – The Case of Hepatitis C' (2019) South Centre Research Paper 85

Lestari SN, 'Implementasi Compulsory Licensing Terhadap Obat-Obatan dalam Bidang Farmasi di Indonesia' (Studi Berdasarkan Doha Declaration on the TRIPS Agreement and Public Health) (Thesis, Master Program on Jurisprudence Diponegoro University, Semarang 2012)

Niesporek A, 'Compulsory Licensing of Pharmaceutical Products & Access to Essential Medicines in Developing Countries' (Thesis**,** Linköping University, Sweden 2005)

Samariadi, 'Pelaksanaan Compulsory Licensing Paten Obat-Obatan Bidang Farmasi di Indonesia Dikaitkan Dengan *DOHA Declaration on the TRIPS Agreement and Public Health'* (2016) 1(2) *De Lega Lata*

Scrutton J, Wallace J, and Wait S, 'Situation Analysis of Viral Hepatitis in Indonesia: A Policy Report' (*Coalition to Eradicate Viral Hepatitis in Asia Pasific,* July 2018)

Sibley A, Han KH, Abourached A, et al. 2015, 'The present and future disease burden of hepatitis C virus infections with today's treatment paradigm' Vol 3 J Viral Hepat 22 Suppl 4

Sulasno, 'Lisensi Hak Kekayaan Intelektual (HKI) Dalam Perspektif Hukum Perjanjian di Indonesia' (2012) 3(2) *Adil Jurnal Hukum*

Umar M, *et al,* 'Diagnosis, Management, and Prevention of Hepatitis C in Pakistan 2017' (2016) 28(4) Journal of Ayub Medical College Abbottabad-Pakistan

Utomo TS, 'Implikasi Pasal-Pasal Pelindung (The TRIPS Safeguards) Dalam UU Paten Indonesia: Kritik, Evaluasi, dan Saran Dari Perspektif Akses Terhadap Obat Yang Murah dan Terjangkau' (2007) 14(2) Jurnal Hukum

Wartini S, 'The Legal Implication of Compulsory License Pharmaceutical Products in the TRIPs Agreement to the Protection of the Right to Health in Developing Countries' (2018) 18(1) Jurnal Dinamika Hukum

Yuswanto S, 'Upaya Mewujudkan Alih Teknologi Melalui Waralaba' (2019) 4(1) UBELAJ

Websites and Blogs

Ardana G, 'Government Releases Compulsory Licensing Regulation' <www.amcham.or.id,> accessed 24 November 2019

Badan POM, 'Badan POM Menyetujui Izin Edar Sofosbuvir, Obat Hepatitis C' <www.pom.go.id,> accessed 20 November 2019

Ellen 't Hoen and Suerie Moon, 'Equity Pricing of Essential Medicines in Developing Countries'<https://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/15thoen_e.pdf> accessed 23 November 2019

Global Business Guide Indonesia, 'Indonesia's Pharmaceutical Industry is in Rude Health' (*Global Business Guide Indonesia*) <www.gbgindonesia.com> accessed 28 October 2019

Kementerian dan Kesehatan Republik Indonesia, 'Situasi Penyakit Hepatitis B di Indonesia Tahun 2017' *Infodatin (Pusat Data dan Informasi Kementerian Kesehatan RI,* 2017) <https://pusdatin.kemkes.go.id/resources/download/pusdatin/infodatin/Infodatin-situasi-penyakit-hepatitis-B-2018.pdf> accessed 4 September 2019.

Kusuma DR, 'Jokowi: 95 Persen Bahan Baku Obat Masih Tergantung Impor' (*Kumparan Bisnis*, 21 November 2019) <https://kumparan.com/kumparanbisnis/jokowi-95-persen-bahan-baku-obat-masih-tergantung-impor-1sIR5Ov5VZt> accessed 21 November 2019.

Oxford Business Group, 'Indonesia Bolsters Domestic Pharmaceuticals Production Capacity' (*Oxford Business Group*) <www.oxfordbusinessgroup.com> accessed 9 November 2019.

Prasetyo WB, 'Obat Hepatitis C di Indonesia Lebih Mahal 10 Kali Lipat Dibanding India' (*Berita Satu*, 29 July 2018) <https://www.beritasatu.com/nasional/503222/obat-hepatitis-c-di-indonesia-lebih-mahal-10-kali-lipat-dibanding-india> accessed 21 November 2019.

World Health Organization, 'Global Report on Access to Hepatitis C Treatment' (*WHO*) <www.who.int,> accessed 28 October 2019

World Health Organization, 'Hepatitis C' <www.who.int> accessed 5 September 2019

World Intellectual Property Organization, 'What is Intellectual Property' <www.wipo.int,> accessed 4 September 2019