THE COMPARATIVE STUDIES OF COMPULSORY LICENSE REGULATION FOR PHARMACEUTICAL PRODUCT BETWEEN INDONESIA AND INDIA

A BACHELOR DEGREE THESIS

By :
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FACULTY OF LAW
UNIVERSITAS ISLAM INDONESIA
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Presented as Partial Fulfillment of the Requirements to Obtain the Bachelor Degree at the Faculty of Law, Universitas Islam Indonesia, Yogyakarta

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Yang bersangkutan,

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MOTTO

يُسْرًا الْعُسْرِمَعَ إِنَّ (5) يُسْرًا الْعُسْرِ مَعَ فَإِنَّ (6)

"Indeed, after the difficulty there is ease, in fact, after that difficulty there is ease."
(Q.S Asy Syarh : 5-6)

الْخَيْرَات فَاسْتَبِقُوا

"Race competition in goodness."
(Q.S Al-Baqarah: 148)

وُسْعَهَا إِلَّا نَفْسًا اللَّهُ يُكَلِّفُ لَا

"Allah never burden someone, beyond his ability"
(Q.S Al-Baqarah: 286)

لِنَفْسِه يُجَاهِدُ فَإِنَّمَا جَاهَدَ وَمَنْ

"And whoever strives, the strives is the benefit for himself"
(Q.S Al-Ankabut:6)

"Do Your Best, and Let God Do The Rest"
(Someone)

"Jatuh 7 kali, Bangkit 8 Kali"
(Someone)

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My Beloved Grandpa, Yarmanis
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All of My Lectures of Faculty of Law, Universitas Islam Indonesia
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TABLE OF CONTENTS

TABLE LIST

ABSTRACT

Patent as one of the protections given by the government to the patent holder for his invention. The protection given by the state is the exclusive right. However, the exlusive right leads the patent holder to the monopoly right which means that not all people can utilize the invention because it needs the patent holder consent. For that reason, Indonesia and India which are the states member of the WTO and also the developing countries used the flexibility of the patent. The flexibility of patent is the kind of option to except and limit the right granted by the patent protection (exclusive right). In the practice, Indonesia and India are commonly used flexibility of patent through the compulsory license to avoid monopoly right. Compulsory license is the kind of license to use the invention without patent holder consent which is granted with a certain procedure. However, there is an exception to give the compulsory license directly such as for the pharmaceutical product because it is related to the public interest. Furthermore, the TRIPs Agreement has already permitted the provision.

The problems of this research are focused on (1) the similarities and differences between Indonesia and India's regulation regarding the compulsory license of pharmaceutical product especially in the matter HIV/AIDS medicines; and (2) legal implication of regulation regarding compulsory license in Indonesia and India especially in the matter HIV/AIDS medicine.

The results of the study show that there are similarities between Indonesia and India as the WTO members. In this matter, they must adopt the same legal basis to implement the compulsory license based on TRIPs Agreement. In addition, they require the requirement to ask to compulsory license are based on the request during the 3 years after granting patent protection. Another similarities are related to the purpose of the compulsory license based on the public interest. In addition, both countries adopted same legal certainty for the pharmaceutical product granted directly without any requirement procedure. However, there are still differences among the members especially Indonesia and India. The differences regarding compulsory license for pharmaceutical product on patent are related to the subject grants the compulsory license. In Indonesia, Ministry through Minister Decision is one of the subjects who has an ability to grant the compulsory license. In another side, India has regulated the subject who is able to grant the compulsory license which is the Controller. In the practice, the compulsory license for pharmaceutical product in Indonesia has not yet been implemented. However, India has already implemented the compulsory license for generic production.

Furthermore, the regulation on compulsory license for pharmaceutical product in patent protection gives the legal implication for Indonesia and India. The first legal implication is in the form of legal certainty for compulsory license in Indonesia and India. The second legal implication is related to the protection for the parties involved in compulsory license. The last implication is regarding the form of utilization of compulsory license in Indonesia and India.

Keywords: Patent, Flexibility of Patent, Compulsory License, and Pharmaceutical Product

CHAPTER I

INTRODUCTION

A. Context of Study

There are several aspects of the Intellectual Property Right such as utility model, industrial design, trademark, service marks, trade names, indication of source, appellation of origin, repression of unfair competition and patent. Patent protection is the one of the main aspects that is usually implemented by almost all of the countries. The patent is a right given to the inventor to give or not to give permission for his or her invention in the technology. The right has granted by the patent not only positive right but also negative right which enables the patent holder to prevent the third party from making or using the product. The positive right means the exclusive right gives legal monopoly for the inventor carry out or not carries out the patent invention in a certain time. In another side, patent in negative exclusive right is a right to prevent others from using the patented invention based on the patent holders consent. As opposed to a positive right utilization, the patent system can neither stop inventors from inventing in respect of subject matter excluded from patent protection, nor prohibit the commercial exploitation and use of several inventions.[1] To prevent the negative right, the states is

[1] World Intellectual Property Organization (WIPO), *Exclusion From Patentable Subject Matter and Exception and Limitations to the Rights,* (Geneva; WIPO Publication SCP/13/3, March 2009) thirteenth session, p. 9

implemented the exception or limitation to the invention, or in another word, it is called as flexibility of patent.

Nowadays, either in national or international level the states have adopted the patent protection automatically include the implementation of the flexibility of patent. The main point of the flexibility is the kinds of exception or limitation of the exclusive right attached to the patent. In other words, the exception cannot contradict and does not make sense with the normal implementation for the patent holder. Also, it does not ignore the third parties interest, which is regulated under Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement and also Paris Convention. Paris Convention is as one of the legal basis concept for TRIPs Agreement. In addition, the exception and limitation of flexibility are allowed or permitted based on the existence of Article 3 regarding National Treatment as mentioned in Article 3 is stated that the state member can except the provision to secure the law and regulation.

However, not all of the inventions gets the exception and limitation. There are two basic reasons to except the patent protection regarding the patent protection which allows the state to fill the different interest among stakeholder. The first, there are provisions that exclude or allow the exclusion. Certain uses of the patent invention from the inventor who will not be processed in the infringement of national are stated also bellow in an international agreement. The second types of exception and limitation has characterized by the fact of the patent protection receiver cannot

stop third parties from using his patented invention, but it is entitled to remuneration against such use. In other words, although the injunctive relief is significantly limited, the right to remunerate against the use of the invention is maintained. Compulsory licenses (or non-voluntary licenses) are often used to put this type of limitation in place. [2]

In other words, the flexibility of patent or in other words the exception and limitation of the patent right itself allowed to be implemented if it is related to the public interest. According to TRIPs, there are two kinds of the subject matter of exclusion. First, it is necessary to protect public order or morality, including when intended to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that necessity is at stake and not just convenience. The second group are including (i) diagnostic, therapeutic and surgical methods for the treatment of human or animals, as well as (ii) plants and animals other than the microorganism, and (iii) plant or animal production essentially biological processes other than non-biological and microbiological process.[3]

Furthermore, regarding the basic mechanism, the requirement system of the flexibility of the patent, the provision of TRIPs Agreement give the wide space for the state members because the mechanism and administration do not provide the additional requirement for the provisions in the TRIPs Agreement. Meanwhile, the obligation to implement flexibility is

[2] *Ibid* p. 3

[3] Denis Borges Barbosa and Karin Grau-Kuntz, *Exclusion From Patentable Subject Matter and Exceptions and Limitation to The Rights,* World Intellectual Property Organization, 2010 p.13

conducted by the state members based on each of the states regulation. Therefore, the regulation in the state nation regarding the Intellectual Property Right especially flexibility of patent protection from one state to another state has different mechanism from patent flexibility. Because it was based on each of their nations and there is no strict provision as the basis of the procedure or mechanism of the patent flexibility, it only mention cannot contradict with the TRIPs Agreement. However, the TRIPs Agreement will be as the basic regulation to implement the Intellectual Property Right because the TRIPs Agreement has become the minimum standard of law enforcement regarding Intellectual Property Right.

Furthermore, the TRIPs Agreement as the legal basis of state members is regulated that the state can limit and except the patent right especially for the invention related to public need. It already supports the state member allowed to implement the exeption and limitation with the existence of Article 31 TRIPs Agreement. It has been mentioned in Article 31 TRIPs Agreement, the state can legalize the use of invention by the third parties (compulsory licenses) or for public interest without having the purpose of commercial or in other words not for commercial use (conducted by the government) without any approval from the inventor. The basic of using compulsory license is not only mentioned in the TRIPs Agreement but also taken into consideration to fulfill the requirement to protect the invention. However, there are two main requirements as the compulsory license system was mentioned in Article 31 TRIPs Agreement. First, it must

make an effort to get the licenses for the commercial requirement in properly. Second, adequate fee must be paid to the right patent holder. [4] In another word, the compulsory license will be granted in the condition for public and national emergency situation, or not using in the non-commercial use. However, the implementation of the compulsory license regulated in Article 31 TRIPs Agreement is still provided the uncertain and unclear provision, because there is no explanation regarding the meaning of the public and non-commercial activity.[5] For that reason, it makes the different interpretation among state members related to the meaning of public and non-commercial activity.

To make it clear, according to The Doha Declaration "the TRIPS Agreement does not and should not prevent state members from taking measures to protect public health".[6] In this regard, the Doha Declaration of the WHO principles have publicly advocated and advanced over the years, namely the re-affirmation of the right of WTO Members to make the using of the public health and enhance access to medicines for poor countries. The Doha Declaration explains several aspects of the TRIPs Agreement i.e. the rights to grant compulsory licenses and freedom to determine the grounds upon which the licenses are granted, the right to determine what constitutes a

[4] Emmy Yuhassarie, *Hak Kekayaan Intelektual dan Perkembangannya*, Pusat Pengkajian Hukum, Jakarta, 2005, p.279

[5] Budi Agus Riswandi and M. Syamsydin, *Hak Kekayaan Intelektual dan Budaya Hukum,* Second Publication, PT. Raja Grafindo Persada, Jakarta, 2004, p. 104

[6] World Health Organization, *The Doha Declaration on The TRIPS Agreement and Public Health,* http://www.who.int/medicines/areas/policy/doha_declaration/en/ accessed on the date September 20th, 2018, 14.20 A.M

national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion in Intellectual Property Rights.[7]

In addition, in the speech of The General Directorate of WTO it is stated that every state members of WTO has the right to organize the flexibility of the patent medicine. The flexibility is referred as the term of compulsory licensing, which are expected to be a solution for the countries, which have obstacle regarding the capability to buy the medicine that already gets patent, or there is no capability to produce the medicine in the local level.[8]

Furthermore, there are several scopes of the patent flexibility such as parallel import, government use, bolar provision, and compulsory license. This thesis explains more deeply regarding the compulsory license because the compulsory license gives the opportunity especially for the developing countries to learn and use the invention in technology, which usually comes from developed countries without need the patent holder consent. Furthermore, it helps the developing countries to provide the affordable price especially for the medicine. Because the advantage from the implementation of the compulsory license makes several countries especially the developing country implement the compulsory license especially in the matter of pharmaceutical product.

The Black Law Dictionary gives an explanation of compulsory license which means "a statutorily created license that allows certain people

[7] *Ibid*

[8] Samariadi, "Pelaksanaan Compulsory Licensing Paten Obat-Obatan Bidang Farmasi Di Indonesia Dikaitkan Dengan Doha Declaration On The TRIPs Agreement and Public Health", Fakultas Hukum Universitas Riau, Vol I No. 2, Juli-December 2016 p. 451

to pay a royalty and use an invention without patentee's permission".[9] Based on the definition above, the state can use or distribute the invention without getting permission to the investor based on a license which has already been agreed. However, it is only for several cases such as regarding the public interest and does not harms the inventor.

In practice, either national or international level the states have implemented the compulsory license in the matter of pharmaceutical product especially in the matter HIV/AIDS medicine. This topic is discussed more deeply in the matter of pharmaceutical product because the compulsory license usually used by the state in the matter of medicines such as HIV/AIDS drugs as the kind of infectious diseases, which is fast contagious to other. If the government is not taking care these diseases, it will be danger and increase more citizen who suffer from HIV/AIDS. Furthermore, HIV/AIDS is related to the public health which is under the government responsibility in taking care of the diseases, based on this reason, the government must provide the medicine to prevent the spread of HIV/AIDS. In other word, the government is expected to provide affordable price of HIV/AIDS medicine for society, to make the medicine of the HIV/AIDS medicine affordable to the society it needs the limitation or exception for the invention which will be affected the price become cheaper than using for public consumption. Because of several states especially the developing countries which is

[9] Dea Melina Nugraheni, *Perlindungan Paten dan Fleksibilitas Persetujuan TRIPs di Bidang Farmasi di Indonesia,* FH UI, 2011 p.25

needed the exception and limitation to minimize the price, then they was adopted the compulsory license to decrease the price in the matter the pharmaceutical product. The developing country which was implemented the compulsory license in the matter of the pharmaceutical product such as Indonesia and India.

This research took the example of the procedure on compulsory license between Indonesia and India because both of them are the same of WTO member who implements the compulsory license based on TRIPs Agreement. In addition, Indonesia and India are the same position as the developing countries but implements the compulsory license in a different way. In addition, both countries have different legal system, which have different way to implement the compulsory license. Furthermore, the compulsory license has already implement in India can be easier to analyze rather than other countries, who has the possibility to conduct the research.

In national level, Indonesia has already ratified the TRIPs Agreement through the Law Number 7 of 1994. The application of TRIPs is one of the state obligations to implement the regulation of the Intellectual Property Rights based on TRIPs Agreement. Especially for patent protection, patent is the part of the intellectual property right also regulate in this regulation. However, the product is not entirely obligated protect by the patent law. The patent itself can except and limit the right through the flexibility of patent regarding the machines. In Indonesia, the protection regarding machine includes as the patent protection because

machine is categorized as the invention in the form of the technology. Judicially, patent was regulated in Law Number 6 of 1989 amendment lastly in Law Number 13 of 2016 on Patent. According to Indonesia Patent Law, it is stated the exclusive right that was given to the state for the inventor or result of their invention in the form of technology. The exclusive right itself is the right for patent holder, so there is no other person that utilizes the right without the holder permission. [10] However, this right may lead the patent holder to the monopoly right. For that reason, Indonesia prevents the monopoly right through the implemenation of compulsory license.

In another side, the patent in India had been changed for a certain time. The patent regulation was established for the first time in the Indian Patents and Design Act 1911 and amendment lastly in The Indian Patents Act 2005. While the Patent Act, especially regarding compulsory license was regulated in Section 84 until 91 India Patent Act. In addition, especially for compulsory license of pharmaceutical product in India also regulates in 92A India Patent Act. The provision introduced under Section 92A, which provides for compulsory license enable exports for a pharmaceutical product to those countries with no manufacturing capacity of their own. Unfortunately, before the patent act was amended this provision failed to fulfill the situation where there is no patent in the importing countries and no requirement for obtaining a compulsory license there. Because of the several failures of the provision then the Indian Patent Act 1970 was amended in

[10] Samariadi, *Op.Cit* p. 449-450.

2005. [11] According to India Patent Act is already clear mentioned regarding the compulsory license must be given to the pharmaceutical product in the condition such as production and export of the pharmaceutical product which is related to the healthiness of the society. [12]

Furthermore, based on Indonesia and India regulation regarding the patent protection has arise the differentiations and similarities because each of the state members can freely implement the patent based on their need but cannot contradict with TRIPs Agreement as mention in Article 1 paragraph 1. Generally, Indonesia and India regulation have several similarities because both of them are same as WTO member that effected to the implementation of the compulsory license in the same legal basis. The legal basis of compulsory license in patent is Article 31 TRIPs Agreement. Furtheremore, the existence of exception and limitation has been regulated in Indonesia and India regulation. In this matter, the state can except and limit the invention through the compulsory license. Especially for the invention related to pharmaceutical product, Indonesia and India gives special treatment that the invention related to pharmaceutical product necessary to grant by state authorization.

However, in the exception and limitation of the rights India gives more specific condition to granting the patent such as importation of manufacture, medicine and drugs with the purpose of experimental research. In another side, Indonesia just gives the parameter of exception and limitation of

[11] Shamnad Basheer, "India's Tryst with TRIPS; The Patents (Amendment) Act, 2005", *The Indian Journal of Law and Technology*, vol 1, 2005 p. 26

[12] India Patent Act,1970 *amended by patent*(Amendment)Act, 2005

the right in a general way. The exception and limitation of the right as mention uses for the education, research, experiment or analysis not prejudicial to the patent owner, for the purpose of the defense and security of the state or urgency in public interest.

In addition, Indonesia and India Regulation also has different treatment especially for patent protection, it happens because of several reasons. The first, there is differentiation point of view regarding the implementation of flexibility because Article 31 TRIPs Agreement still not yet has the explanation regarding the public and non-commercial use as the object to gives the exception and limitation of the patent. So both of the countries which are implemented the flexibility of patent based on their interpretation. As the result, each of regulation in the state has difference one to another. The second, the regulation Indonesia and India have the different interpretation each of countries regarding flexibilities because they have the different need. In addition, India based on common law in other side Indonesia has adopted the civil law. The legal system between both of countries directly gives a legal implication for them to implement the patent protection also the way of them to solve the problem. In Indonesia who has adopted civil solve the problem base on regulation, in another side India who has adopted common law base on judge decision. The legal system which have been adopted by both of countries not the one and only as the background which arises the differentiation between Indonesia and India, which is effected the procedure to grant the compulsory license has several differences each another.

Other reason as the background is regarding the need of every countries and condition of technology in India more developed than Indonesia and also it related to the society needs.

The arising of similarities and differences between Indonesia and India to implement the compulsory license in the matter of pharmaceutical product especially HIV/AIDS arises the legal implication from the different way to implement the regulation. Either Indonesia implements the compulsory license based on their need under Law Number 13 of 2016 arises the impact which is also different with the Indian Patent Act under 1970 amended lastly in 2005. The legal implication also discussed in this research to identify the effect whose arises either from Indonesia regulation or India regulation.

There are several differences and similarities regarding the implementation of a compulsory license in Indonesia and India in the matter of pharmaceutical product especially HIV/AIDS medicine whose also gives the legal implication to the each of the state has many interesting to discuss. Even Indonesia and India has the same legal basis to implement the Patent Protection, which is come from the TRIPs Agreement, but both of the countries still have differences which are interesting to discuss in this research.

B. Problem Formulation

This Research, focuses on two main questions, as follows:

1. What are similarities and differences between Indonesia and India's patent regulation regarding the compulsory license of pharmaceutical product especially in the matter HIV/AIDS medicines?
2. What are the legal implications of patent regulation regarding compulsory license in Indonesia and India especially in the matter HIV/AIDS medicine?

C. Research Objective

There are several purposes of the research i,e. The purpose of the research are consist of:

1. To identify the similarities and the differences between Indonesia and India on patent regulation regarding the compulsory license of pharmaceutical product especially in the matter HIV/AIDS medicine.
2. To analyze the legal implication arises from Indonesia and India on patent regulation when both of countries are regulated the compulsory license of pharmaceutical product especially in the matter HIV/AIDS medicine.

D. Definition of Term

Basically, patent is an exclusive right given by state for the inventor to give or not to give his invention in the form of technology which is protected by the state for protecting his or her invention. According to Oxford dictionary, it is stated that: [13]

> *"Patent means a government authority or license conferring a right or title for a set period, especially the sole rights exclude others from making, using or selling an invention."*

In addition, Patent according to black dictionary means:

> *"The right to exclude others from making, using, marketing, selling, offering for sale or importing an invention for a specified period (20 years from the date of filing), granted by the federal government to the inventor if the device or process is novel, useful and non-obvious."*

The World Intellectual Property Organization (WIPO) defines a patent as follow:[14]

> *"A patent is a document, issued, upon application, by a government office (or a regional office acting for several countries) which describes an invention and creates a legal situation in with the authorization of the owner of the patent."*

Patent according to Earl W. Kintner and Jack L. Lahr's opinion is an agreement between the inventor and the public represented by the federal government: in return for a full public disclosure of the invention. The inventor is granted the right for a fixed period time to exclude others from making, using, or selling the defined invention in the United States.

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[13] English Oxford Living Dictionaries, https://en.oxforddictionaries.com/definition/patent accessed on Oct. 18th, 2018 at 8.13 PM.

[14] World Intelectual Property Organization, *World Intellectual Property Organization: Intellectual Property Handbook*, WIPO Publication No. 489 (E), 2004, p.17

It is a limited monopoly, designed not primary to reward the inventor (this may or may not follow), but to encourage a public disclosure of inventions so that after the monopoly expires, the public is free to take unrestricted advantage of the invention.[15]

According to Webster's New Twentieth Century Dictionary of the English Language Unabridge, it is stated that: [16]

> *"Something invented; specifically (a) something thought up or mentally fabricated; falsehood; (b) something originated by experiment, etc; a new device or contrivance."*

In another word, patent is a document open examination which is granting certain right of privilege, Moreover, latter of patent is a document granting the monopoly right to produce, use, sell, or get profit from an invention, process, etc for certain number of year.

In addition, according to Indonesia Dictionary patent means the right which is given by the state to someone for certain innovation using by him or herself and protected from imitation and piracy. [17]

According to Indonesia Law as stated in Article 1 Law Number 13 of 2016 on patent, it defines: [18]

> *"Patent is the exclusive right which is given to the state because of the result of the invention in the matter of the technology for certain time to implement his or her invention to other parties."*

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[15] Dea Melina Nugraheni, *Op. Cit* p.23

[16] Noah Webster, *Webster's New Twentieth Century Dictionary of the English Language Unabridged*, quoted on Dea Melina Nugraheni, *Perlindungan Paten dan Fleksibilitas Persetujuan TRIPs di Bidang Farmasi di Indonesia*, FH UI, 2011 page 23

[17] KBBI, https://kbbi.kemdikbud.go.id/entri/paten accessed on October 18th, 2018 at 8.18 PM

[18] Indonesia, Law Number 13 of 2016 on Patent. Article 1 paragraph 1

In another side, India Patent Act, 1970 amended lastly in 2005 defines patent for any invention granted under this act. As menioned in India Patent Act, the term of patent is also known as ‘new invention'. The explanation is, as follows: [19]

> *"Any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification."*

The right which is granted by the patent protection not only a positive right but also negative right. The negative right or monopoly right is prevented by state members through patent flexibility. Flexibility or in other word as the exception or limitation of The provision or regulation which gives the opportunity to provide special characteristic that it is diferent to other common provision. However, the strict definition regarding the flexibility is still not provided either in TRIPs Agreement or Paris Convention that describes or explains the meaning of flexibility especially in the matter of patent protection.

The term of flexibilities defines, there are different options through which TRIPs obligation can be transposed into national law. It means, the national law can be implemented in their national level. This definition would be effectively implement through the scope of the concept with the following elements such as (i) it highlights the ideas of various options for means of implementation; (ii) it refers to the legislative

[19] India Patent Act,1970 *amended by patent*(Amendment)Act, 2005

process of implementation, reflecting to the first step to the advantage of given flexibility is incorporating it into the national law; (iii) it refers to the reason for flexibility, which is to accommodate national interest and; (iv) it reflects which is given flexibility needs to be compatible with the provisions and principles of the treaty.[20]

Furthermore, there are several ways to give exception or limitation to the patent right which is one of them have implemented through compulsory license. The definition of the compulsory license is the permission that given by authorizes subject to implement the patent or to use the invention created by the inventor that have already get patent protection without the permission of the inventor or patent holder because of public interest. In addition, the compulsory license defined by Black Law Dictionary is:[21]

> *"A statutorily created a license that allows certain people to pay a royalty and use an invention without patentee's permission."*

The exception and limitation of patent right usually used by several states in the matter of pharmaceutical product such as medicine. Pharmaceutical product usually uses because it is related to human life, so it can get exception and limitation. The definition of pharmaceutical means the learning of science regarding the production of the

[20] Hans Georg Bartels, *Health Related Flexibilities in The Intellectual Property System,* World Intellectual Property Organization (WIPO), 2016 http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=142068 accessed on November 9th, 2018 at 13:35 PM

[21] Brayn A. Garner, *Black's Law Dictionary,* Tenth Edition, United States of America, p.1060

medicine which consists of collecting, canning and standardizing of the medicinal ingredients, compounding drugs, also preparing pharmaceutical process into certain forms until it is ready to be consumed as a medicine, as well as the development of the medicine including the science and technology making drugs in the form of preparation can using using and giving to the patients.[22]

The pharmaceutical product according to the World Health Organization is more known as medicines or drugs, that become are a fundamental component of both modern and traditional medicine. It is essential that such product products are safe, effective, and good in quality. Moreover, they and are prescribed and used rationally. [23]

In another side, the definition of the pharmaceutical product is also stated in India Patent Act. 1970 amended lastly in 2005 as follows:[24]

> *"Pharmaceutical product means any patented product, or product manufactured through a patented process, of the pharmaceutical sector, needed to address public health problems and shall be inclusive or component necessary for their manufacture and diagnostic kits required for their use."*

E. Theoretical Framework

One of the scopes of the Intellectual Property Right is patent protection, which is as the exclusive right that was given to the state to an

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[22] Dianti Nur Ameliah, https://www.academia.edu/9778247/Definisi_dalam_farmasetika published on May 24,2012 accessed on October 21nd, 2018, at 11.27 AM

[23] World Health Organization, *Pharmaceutical Products,* http://www.who.int/topics/pharmaceutical_products/en/ accessed on October 21nd, 2018 at 11.00 AM

[24] Explanation article 92A paragraph 3 India Patent Act,1970 *amended by patent*(Amendment)Act, 2005

inventor to protect his or her invention in the matter of the technology. Patent has already regulated in the Paris Convention as the basis of TRIPs Agreement, which is automatically implemented by state members who also participate as the member of WTO. According to Paris Convention as legal basis regulates the compulsory license in Article 5A, it is stated:[25]

> *"Every state may take the legal action or legislation that regulate the administration procedure of compulsory license. The compulsory license is intended to prevent the abuse which may cause by the exclusive right that given by patent, for instance not implemented the patent or the implementation not good enough."*

In addition, TRIPs Agreement as another legal basis is mentioned in Article 1 TRIPs Agreement that:

> "*Members shall give effect to the provisions of this agreement. Members may, but shall not be obliged to, implement in their law more extensive protection that is required by this Agreement provided that such protection does not contravene the provisions of this agreement. A member shall be free to determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice."*

According to the Article 1 in TRIPs Agreement, it gives clear explanation, the state member must implement the provision under the TRIPs Agreement in line with TRIPs Agreement or in other words, cannot contradict with TRIPs Agreement. Furthermore, the WTO members must extend patent protection to all inventions, whether the product or process, in all fields of technology. The term of patent protection must be at least 20 years from the date of filing the applications. Moreover, patent rights must

[25] OK. Saidin, *Aspek Hukum Hak Kekayaan Intelektual (Intellectual Property Rights),* Revised Edition, Rajawali Press, Jakarta, 2015, p 424

also be available without discrimination as to the place of invention, the field of technology, and whether products are imported or processed locally. [26]

Under TRIPs Agreement as the legal basis to implement Intellectual Property Right especially patent protection, there are two kinds of the right which consist positive right and also negative right. Positive right is the kind of the exclusive right means the right to give or not to give permission from using the invention that are protected under patent protection. In another side, The negative right is related to the monolopy right means not all of the people can utilize the invention because it needs patent holder concent. Because the patent holder has exlusive right to prevent other using the invention, then under the TRIPs Agreement there is special provision to prevent the negative right through exception and limitation of the inventions. In the practice, several countries such as Indonesia and India was implemented the exception and limitation as the kind to flexible the patent right and prevent the monopoly right arises from the exlusive right.

In practice, Indonesia and India also adopted the same system, both of them not only regulates the right to the invention but also regulates the exception and limitation of the exclusive right to patent holder which is referred to Article 30 and 31 TRIPs Agreement as the legal source to implement the exception and limitation of patent protection. However, TRIPs Agreement does not give strict regulation and explanation

[26] Mitsuo Matsusshita, Thomas J. Schoenbaum and Petros C. Mavroidis, *The World Trade Organization Law, Practice and Policiy,* second edition, The Oxford University Press, United States, 2006 p. 726

regarding the procedure to give exception and limitation of patent protection. It only explains the state can freely implement the exception and limitation based on their state need but cannot contradict with general provision in the TRIPs Agreement. Therefore, the provision related to implementation of the exception and limitation in every state was based on their national interest, the regulation will be permitted as long as is not contradict to the general provision of the TRIPs Agreement. For that reason, it arises several differences among state members.

Generally, there are several ways to accept and limit the Patent right such as parallel import, government use, bolar provision, and compulsory license. Compulsory license is usually used by the state especially in developing countries to except and limits the patent right in the matter of public interest. The developing countries take view which the compulsory license should be required if the public interest is injured due to an abuse of patent monopoly. For example, if a company that has the patent in the area in which there is no competing technology deprives society of its benefits or unduly raises the price of the patented product, a national authority should be able to order compulsory licensing.[27] The compulsory license is the kind of permission for third parties without the consent of the patent holder to produce or use the invention. The permission can be conducted base on several requirements such as the emergency situation in the

[27] *Ibid* p. 728

matter of society healthiness. The compulsory license is also intended to protect the public interest from the negative impact of the patent protection in the matter of medicines.[28] Furthermore, Naomi A. Bass argues, the compulsory license is a very effective strategy for the developing countries to get access of the cheap medicines. He also argues based on the research compulsory license can decrease the medicine price around 75%.[29]

As mentioned in previously, another legal basis for several countries to implement the compulsory license to except and limit the patent right is referring to Article 31 TRIPs Agreement. According to Article 31 TRIPs Agreement, the compulsory license will be given in condition of the national emergency and for public or in other words not using in the non-commercial use. However, the implementation either in the matter of national emergency or non-commercial used is not explained yet in the TRIPs Agreement.[30] Even though the state has implemented the flexibility in the same source and purpose but every single state has a different implementation to treat the flexibilities based on their interpretation. It was happened because of measures which is adapted the patent law to specific industries or problems allows the solution to the inefficiencies inherent in a uniform system. In addition, the differentiation was happened because

[28] Tomi Suryo Utomo, "Implikasi Pasal-Pasal Perlindungan (The TRIPs Safeguards) Dalam UU Paten Indonesia: Kritik Evaluasi dan Saran dari Perspetif Akses Terhadap Obat yang Murah dan Terjangkau", *Jurnal Hukum* No.2 Vol 14, Fakultas Hukum Universitas Janabadra Yogyakarta,2007 p.288

[29] Naomi A. Bass, *The Implication of the TRIPs Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century,* quoted from Tomi Suryo Utomo, *Loc.Cit*

[30] Budi Agus Riswandi and M. Syamsydin, *Loc. Cit*

every country has different views on the balance between incentives to the invention and the need to access the invention. The different point of view happens base on how every innovation and access are respected but maybe reflect the developed need of the countries whom have a different need in each of the states.[31]

Furthermore, the unclear explanation regarding the provision in the TRIPs Agreement makes every state has different interpretation regarding the national emergency and non-commercial used, which has affected the different implementation of a compulsory license, especially in Indonesia and India. In Indonesia, The existence compulsory licensing especially in the pharmaceutical product is an important thing to implement, because according to Article 28 H constitution 1945 determine the healthiness as the basic right of every person also the condition of public health which needs the availability of the medicine with the affordable price. It means the government has a liability to take care of every citizen in the healthy condition. [32] If the condition of several citizens needs medicine, the government should provide the medicine to protect and save the society. When this situation is happening, it needs the compulsory license as the basis to except and limits the patent protection so directly the state can be used and provide based on their needs. The regulation regarding compulsory

[31] Sarah R. Wasserman Reject, "Evaluating Flexibility in International Patent Law", Vol. 65;153, Faculty College of William & Mary Law School, Faculty Publication, 2013 p. 158

[32] Samariadi, *Op Cit*, p. 452

license especially for in Indonesia was regulated in Article 81 until 107 Law Number 13 of 2016 on Patent.

In another side, India was implemented compulsory license which exists in chapter XVI India Patent Act 1970. It was stated, any person can ask the compulsory license with the reason such as the reason of the public with respect to the patented invention have not been satisfied, that the patented invention is not available to the public at a reasonably affordable price or the patented invention is not existed in the India territory. In addition, according to Section 92 stated the government must be granted in respect of any patent, irrespective of the time that has elapsed since the granted of such patent, related to the case of; (a) national emergency; (b) extreme urgency; or (c) public non-commercial use.[33] Futhermore, India Patent Act provides specific provision regarding pharmaceutical product as stated in Section 92a which is permitted for using compulsory license in the matter of pharmaceutical product.

Generally, Indonesia and India permitted the compulsory license for several reasons and purpose which in line with the same source such as TRIPs Agreement and the Paris Convention. One of the implementations of a compulsory license is related to the pharmaceutical product because pharmaceutical product is related to the citizen life, which must be protected by the government. Especially in India Patent act already explain

[33] Shamnad Basheer, "Compulsory Licence Regime in India; Past, Present, and Future", *Electronic Journal,* July 2005

the compulsory license for export the pharmaceutical products, which have been patented. The using of the compulsory license for example in the matter of the pharmaceutical product is HIV/AIDS medicine because the HIV/AIDS as the serious disease which is easy to spread if there is no attention from government to provide the medicine as the kind of the prevention effort to minimize the victim. Furthermore, to provide the medicine for HIV/AIDS the government must serve the medicine at the low price through the limitation and exception of the patent invention, which is possible through the compulsory license because it related to someone life. Those reasons make the state member especially developing countries such as Indonesia and India was adopted and implemented the regulation regarding the compulsory license.

Furthermore, the regulation between Indonesia and India to implement the compulsory license in pharmaceutical product such as for HIV/AIDS medicine not only have similarities but also it have several differentiations, which is compared in this paper. In addition, the similarities and differences between Indonesia and India regulation to implement the compulsory license arise the legal implication which is identified more deeply in this paper.

F. Research Methodology

1. Type of Research

The research is categorized into using the normative legal research, means the research using the conceptual and developed base on positive law namely regulation and doctrine related to the patent protection. The regulation used Indonesia regulation in Law Number 6 of 1989 amended lastly in Law Number 13 of 2016 on Patent and India Patent Act year 1970 amended lastly in 2005.

2. Object of Research

The object of this research in this matter consists of:

a. The similarities and differences between Indonesia and India on patent regulation regarding the compulsory license of pharmaceutical product in the matter HIV/AIDS.

b. The legal implication of the implementation compulsory license on patent regulation in Indonesia and India regarding the pharmaceutical product in the matter HIV/AIDS.

3. Source of Data

The data resources use secondary data. The data were obtained from several substances, i.e.

a. The primary legal material is legal sources which is legally binding related to the object of this research as follow as:

1. TRIPs Agreement
2. Paris Convention for Industrial Property

3. World Intellectual Property Right Handbook
4. Indonesia Regulation on Law Number 6 of 1989 amended lastly in Law Number 13 of 2016
5. India Patent Act year 1970 amended lastly in 2005
6. The others law and regulation regarding this research.

b. Secondary legal material which explains the nature of the law towards the primary law in the form of the textbooks, literature studies, journal and electronic legal material, and other scholars opinion and material related to the object of this research.

c. Tertiary legal materials are material which gives the direction and/or explanation towards primary legal material and secondary legal materials which consist of:
1. Black's Law Dictionary
2. Oxford Dictionary, and
3. Others dictionary.

4. Method of Data Collecting

The method of the data collection in this research is the literature study. Literature studies as the main data to get information related to the topic of this research. The information is obtained from scientific books, dictionary, research report, journal, and several regulations, as the general regulations are TRIPS Agreement, Paris Convention, Indonesia and India regulation regarding patent law. In addition,

the method of the data collection uses document studies, which means the data are collected by learning from the document in taking the data or information, which is related to the related to the research.

5. Method Approach

The approach method used in this research is statutory research approach in which the approach methods are to understand the problem based on the statue or the regulation of the patent law in several regulations that was already implemented by several countries either in Indonesia or India. In addition, it is used as a comparative approach in which the approach methods are to understand the materials by identifying the similarities and differences and compare each of the state regulation regarding the compulsory license.

6. Legal Material Analysis

This research is used qualitative analysis methods. The data were collected and elaborated in the form of describtion and explanation. Then, it was examined or reviewed based on the expert opinion, legal theories, relevant legal studies, article of the statue and the argument of the researcher itself in order to obtain the significant and scientific conclusion. The legal material obtained from this research was presented and elaborated qualitatively by ways as following:

a. The legal materials was classified and collected based on the research problem

b. The result of the classification legal material was complied systematically
c. The systematic legal materials was analyzed to be formulated as basic in conclusion formulation

G. Originality of Research

The researcher originally conducted this research, then it is discussed The Comparative Studies of "The Compulsory License Regulation For Pharmaceutical Product Between Indonesia and India". In this thesis is different from others thesis such as the thesis written by Ida Rofidah from the Faculty of Syariah and Law at Universitas Islam Negri Syarif Hidayatullah Jakarta in the title "Penyalahgunaan Perjanjian Lisensi Merek dalam Praktek bisnis Hak Atas kekayaan Intelektual" that it is different from the researcher object of the research because this research object in the matter of compulsory license for patent regulation. In addition, this thesis is different from the thesis from Aditya Galih Utama from Faculty of Law at Universitas Muhammadiyah Surakarta in the title "Tinjauan Yuridis Perjanjian Lisensi Perangkat Lunak Microsoft Antara Universitas Muhammadiyah Surakarta Dengan CV. Trijaya Technology Bizniz" that the object is different that He write on Microsoft between UMS and CV. Trijaya Technology Bizniz however this thesis is regarding Pharamaceutical Product that compared between Indonesia and India. In the last, this thesis is also different from thesis write by Agnes Ivonne de Fretes from Faculty of Law at Universitas Airlangga Surabaya in the title "Beberapa

Masalah yang Timbul Dari Pemberian Lisensi Wajib Menurut Undang Undang Nomor 6 of 1999 on Patent. However, it is different from this thesis because the legal basis for Indonesia regulation in this thesis is Law Number 13 of 2016 on Patent.

H. Structure of Writings

This research is compiled systematically into 4 (four) chapters with the following details:

Chapter I is Introduction which consists of these following parts: Study Background, Problem Formulation, Research Objective, Definition of Term, Theoretical Framework, Method of Legal Research, Originality of Research and Structure of Writing.

Chapter II is Theoretical Review. This chapter elaborates general overview on theory of the patent especially the concept regarding the patent protection, flexibility of the patent, theory and procedure of the compulsory license on patent regulation include the procedure in Indonesia and in India, also explain the islamic perspective regarding intellectual property right include Fatwa MUI.

Chapter III is Findings and Discussion. This chapter contains discussions and findings on specific overview of the comparative studies between compulsory license between Indonesia and India regulation regarding the compulsory license for the pharmaceutical product in the matter HIV/AIDS medicine. Furthermore, it also

discusses the legal implication from the implementation in Indonesia and India's regulation regarding the compulsory license especially in pharmaceutical product especially in the matter HIV/AIDS medicine.

Chapter IV is a conclusion, which contains the conclusion and recommendation which is obtained from the previous analysis done previously.

CHAPTER II

THEORETICAL REVIEW

A. The Concept of Patent

1. Definition of Patent

The patent comes from the word of *patere* which means open up or extrovert. The opposite term from this word is *laten* mean hidden or veiled. The concept of open means the inventor free-for-all of his knowledge and technology for the purpose of the improvement of the society, as the replacement the inventor is getting the exclusive right during a certain time.[34] Whereas, the term of patent in the Dutch language is known with the term of *octrooi,* it comes from the Latin of *oktroi* from the term of *auctor/auctorizare*. The meaning of *auctor* is similar to the term of open. The term *auctor* means the invention, which granted by patent, is opened to the public. The opening of patents for the public does not mean all of the people free to implement the invention, only thorough the permission of the patent holder someone can implement and utilize the invention. After the expired time of patent protection the invention becomes public. [35]

Basically, the patent is an exclusive right given by the state for the inventor to give or not to give permission to use or utilize his invention in

[34]Slamet Yuswanto, *Memahami Paten Berdasar Undang Undang Nomor 13 tahun 2017 dan Perjanjian TRIPs,* CV Keni Media, Bandung, 2017, p. 1

[35] Endang Purwaningsih, *Perkembangan Hukum Intellectual Property Rights.* First Edition, Penerbit Ghalia Indonesia, Bogor, 2005, p. 26

the form of the technology which is protected by the state for protecting his or her invention. According to the Oxford Dictionary, it is stated that: [36]

> *"Patent means a government authority or license conferring a right or title for a set period, especially the sole rights exclude others from making, using or selling an invention."*

In addition, patent according to Black Law Dictionary defines the meaning of patent as follows:[37]

> *"The right to exclude others from making, using, marketing, selling, offering for sale or importing an invention for a specified period (20 years from the date of filing), granted by the federal government to the inventor if the device or process is novel, useful and non-obvious."*

According to World Intellectual Property Organization (WIPO) defines a patent as follow:[38]

> *"A patent is a document, issued, upon application, by a government office (or a regional office acting for several countries) which describes an invention and creates a legal situation in with the authorization of the owner of the patent."*

In addition, World Intellectual Property Organization (WIPO) already defines the definition regarding patent such as:

> "*An exclusive right granted for an invention, which is product, or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application."*

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[36] English Oxford Living Dictionaries, https://en.oxforddictionaries.com/definition/patent accessed on Oct. 18th, 2018 at 8.13 PM.

[37] Brayn A. Garner, *Black's Law Dictionary,* Tenth Edition, United States of America, 2014, p.1300

[38] World Intellectual Property Organization, *World Intellectual Property Organization: Intellectual Property Handbook*, *Op. Cit* p.17

Whereas, the World Intellectual Property Organization (WIPO) also gives an explanation regarding the exclusive right here as follow:[39]

> *"A patent owner has the right to decide who may or may not use the patented invention for the period during which it is protected. Patent owners may give permission to, or license, other parties to use their invention right to someone else, who then becomes the new owner of the patent. Once a patent expires protection ends and the invention enters the public domain. This is also known as becoming off patent, meaning the owner no longer holds exclusive right to the invention, and it becomes available for commercial exploitation by others."*

As the mention in WIPO, it clearly explains the definition of the exclusive right as the right of the patent owner to give or not to give permission to other from using of the invention. The term of the exclusive right usually called as positive right. Opposite of that, there is the negative right which is also arisen from the patent protection. The definition of the negative right is the right to prevent others from using the patented invention because it needs the patent holder consent, as opposed to positive right utilization, the patent system can stop the inventors from inventing in respect of the subject matter excluded from patent protection nor prohibit the commercial exploitation and use of such inventions.[40]

In national level, there are several definitions regarding the patent which is interpreted based on their every national regulation. According

[39] World Intellectual Property Organization, *What is Intellectual Property?, http://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf* accessed on November 2nd, 2018 at 16.30 PM

[40] World Intellectual Property Organization, *Loc.Cit*

to Indonesia Patent Law as stated in Article 1 Law Number 13 of 2016 defines a patent as follow: [41]

> *"Patent is the exclusive right that given to the state because of the result of the invention in the matter of technology that for certain time to implement his or her invention to other parties."*

In another side, India Patent Act 1970 amended lastly in 2005 defines patent for an invention granted under this act, the term of the patent also known as 'new invention', it is stated that: [42]

> *"Any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification."*

In addition, the definition of patent according to several scholars defines a patent as follows:

a. According to Octroiwet's opinion, patent right is the special right given for someone on the request for person who was created a new product with the new process or new repair from the product or the ways of working.[43]
b. According to Adrian Sutedi's opinion, patent right is the special right given by the state to the inventor for his or her invention in the matter of technology, for the duration which has been determined to carry out the invention themselves or give approval

[41] Indonesia, Law Number 13 of 2016 on Paten. Article 1 paragraph 1
[42] India Patent Act,1970 *amended by patent*(Amendment)Act, 2005
[43] Utsman Ali, *Pengertian Hak Paten,* http://www.pengertianpakar.com/2015/04/pengertian-hak-paten.html accessed on November 30, 2018, at 15.40 PM

for others to carry it out. This patent is granted for new invention that contains inventive step and can be applied in industry.[44]

From several definitions above, it can be concluded that the patent is the special right namely exclusive right for the protection of the invention, which is already created by the inventor in the matter of technology. Furthermore, the exclusive right in the patent protection has the meaning regarding the right of the patent holder to give or not to give permission for other parties from using, utilizing, and producing his or her invention.

2. Legal Basic of Patent

Patent protection as one of the scopes Intellectual Property Right has several legal basis such as Paris Convention and TRIPs Agreement. Paris Convention regulates regarding the right in industrial scope which has been ratified on March 20, 1883. The object of the protection according to this convention such as: patent, utility models, industrial design, trademark, trade names, the indication of origin.[45] In general, the Paris Convention has regulated intellectual property rights for use to other state citizens for conventions, which allows the same level and the same solution to violations. The priority right is given the applicant from one contracting country the right to use the first application submission date

[44] *Ibid*
[45] OK. Saidin, *Op.Cit* 422

(in one contracting country) as an effective receipt date in another contracting country providing other application submitted within a certain time of the original application (6 months for trademarks and designs, 12 months for patents).[46]

In addition, the TRIPs Agreement actually is one of legal basis in patent law and the legal basis of state member to implement the Intellectual Property Right especially patent protection. In addition, the TRIPs Agreement is contained the strict regulation which is felt by the developing countries. However, there are several articles and provision that can be used as the gap of securities or safeguard. It means, there is an opportunity for every state to conduct protection of intellectual property right which is adopted base on the national interest. However, the implementation is cannot contradict with the TRIPs Agreement.[47] It is in line with Article 1 paragraph 1 TRIPS Agreement, it is stated that:

> *"Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."*

According to the basic principle in Article 1 paragraph 1 TRIPs Agreement is mentioned the state member implement the protection of Intellectual Property Right based on TRIPs Agreement. However, the

[46] Raditya Adi Nugraha,*Op.Cit* p.53

[47] Muhammad Djumhana and Djubaedillah, *Hak Milik Intelektual,* First Publication, PT. Citra Aditya Bakti, Bandung, 2014 p. 160

implementation of each regulation is based on the state members legal system, which is considered appropriate to each of the state legal system and practice. In addition, any kind of implementation is permitted as long as is not contradict with the TRIPs Agreement.

In specifically, patent as the part of Intellectual Property Right especially on patent was regulated and explained under TRIPs Agreement which gave the main point regarding the patent related to the inventions product in the fields of technology including the patent right. In addition, the patent right cannot have the characteristic of discrimination. It is stated in line with Article 27 paragraph 1 TRIPs Agreement, it is stated that:

> *"Subject to the provisions of paragraph 2 and 3, patents shall be available for any inventions, whether products or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of article 65, paragraph 8 of article 70 and paragraph 3 of this article patent shall be available and; right enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced "*

According to Article 27-35 TRIPs Agreement, there are several standards to grant the patent, and there are several uses also the scopes to implement patent protection as follows: [48]

[48] Khoirul Hidayah, *Hukum Hak Kekayaan Intelektual,* Setara Press, Malang, 2017 p. 70-71

a. The patent is an exclusive right given from the state to all of the invention, which is include the product and the process in the matter of technology.
b. The result of invention considered as the new patent, if it is included the inventive step. In addition, the invention can be implemented in industry, and it includes in the matter of technology either made in national or imported to other states.
c. The right of the patent holder prevents the third parties without permission from patent holder to produce, use, and offer to sell or import to other states.
d. State member can be refused to grant the patent with the purpose of protecting the public order or morality, including to protect the human, animals, plants, and health. In addition, it has the purpose to prevent the serious impact which is possible to accrue the environmental, as long as the provision made by the state member is not prevented by the domestic regulation.
e. The patent holder has the right to transfer, inherit and held the compulsory license.
f. The government can allow the utilization of patent by third parties through the permission of patent holder for the reason of public interest (lack of work, public health, economic development, and national defense).
g. The duration of patent protection is during 20 years.

Based on the TRIPs Agreement the patent protection must be protected for the invention which already fulfills the requirement in the form of the new technology involves the criteria to become the invention such as novelty, inventive step and the inventive must be accepted by the industry. The invention that has already fulfilled the requirement included the product and process. Furthermore, the invention must be protected for at least 20 years.[49] In addition according to several scholars such as Smith, he explains patent as the function of the basic justification on the patent system such as:[50]

a. Technology advance of the countries and economic development;
b. Stimulation of indigenous industrialization;
c. Patent can contribute to technological and economic through licensing in other countries;
d. Patent is helping in the dissemination of technological information;
e. Availability of patent protection provides an inflow of technology from other countries and incentive for investment.

In line with Smith's opinion, patent has the important role to speed up the development of socio-economic in the national level. In this matter,

[49] World Trade Organization, *Intellectual Property: Protection and Enforcement* https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm accessed on November 10th, 2018, at 14.58 PM

[50] Endang Purwaningsih, *Seri Hukum Hak Intelektual Hukum Paten,* First Edition, Mandar Maju, Bandung, 2015, p.2

patent supports the spread of technology through the documentation and publication. In addition, patent is encouraging the development of the industry and infestation. The consideration of the patent could encourage the development of the economy also strengthened by Edith Penrose's opinion, as the economic expert, he is stated that:[51]

> *"Almost of technology needs for the industrial development that already patented, and the patent itself has by the companies located in the industrial countries. The disclosures of technology occur in the administration of patent that constitutes the general knowledge, which rarely can be applied without technical assistance from the patent holder. The companies will not give the procedure also the technical assistance with the requirement that may take the protection granted by their patent."*

In the national level, states member has been regulated the protection of patent law through their each of regulation. For instance, Indonesia has regulated the patent protection through the Law Number 13 of 2016 on Patent. Furthermore, the implementation of patent law based on Law Number 13 of 2016 regarding Patent has several important elements. The first, patent is an exclusive right, means patent as the material right which has characteristics of intangible assets constitute as special right, but it leads to the monopoly right. The meaning of monopoly means not all of the people can be used or implemented the invention because it needs the patent holder consent. Second, patent is given by the state to the inventor. It means for the purpose of getting

[51] T. Mulya Lubis and M.Richard Bukbaum, *Peranan Hukum Dalam Perekonomian di Negara Berkembang,* quoted from Slamet Yuswanto, *Memahami Paten Berdasar Undang Undang Nomor 13 Tahun 2017 dan Perjanjian TRIPs,* CV Keni Media, Bandung, 2017, p.3

the patent protection, the inventor is necessary to apply for the patent registration. If the registration is already completed in the matter of substantive side and administrative side, the inventor will get the exclusive right from the government; patent grant by the government for the technology investment. Meanwhile, the patent is given by the government only specify in the matter of technology, outside the technology cannot be requested for the patent protection. Third, the patent gives the time duration to implement the invention or to give the approval to other parties to implement the invention. It means for the inventor who implements the invention by himself or gives the permission for other people to implement his invention. [52]

In another side, India also regulates the patent protection through the India Patent Act 1970 amended in 2005. India's patent policy is focused on balancing developmental concerns with the need for promoting innovations. India viewed patents as a tool for economic development and restricted the scope and term of patents.[53] In addition, the patent as knowing in Indian Patent Act as defines as 'invention' means a product or process involving an Inventive step and capable of industrial application. Furthermore, the patent system is established a definite procedure for the grant of patents. The procedure for obtaining patent protection is highly relevant from the perspective of an inventor.

[52] Budi Agus Riswandi dan M. Syamsudin, *Op.Cit* p.125

[53] *An India Patent Act; An Overview,* http://shodhganga.inflibnet.ac.in/bitstream/10603/137841/9/09_chapter%202.pdf accessed on December 6th, 2018 at 1.01 PM

The Patent Act provides a full-fledged procedure to ensure that patent is granted to a person who applies for a patent and to make sure that the patent rights are not misused. The patent procedure comprises four main steps, namely: application for the patent; examination of the application; opposition to the grant of patent; and finally grant of patent. The right is granted by the state to the patent holder shall be for a period of 20 years from the date of filing of the application for patent. In addition, an applicant is requested to file an international patent application through the procedural formalities laid down in the patent co-operation treaty. According to Indian Patent Act, an application for a patent can be made by any person claiming to be the true and first inventor of the invention, any person is being the assignee of the person claiming to the true and first inventor or by the legal representative of any deceased person who immediately before his death was entitled to make such an application. In addition, this application for the patent is not mandatory that only an inventor can apply for and get a patent over an invention.[54]

3. The Kind of Patent

There are three types of patent that consist of:[55]

a. Utility patents: These are patents that cover how a product, process, composition, machines and manufactures which are new and useful.

[54] *General Principles Of Patent Law,* http://shodhganga.inflibnet.ac.in/bitstream/10603/21666/4/chapter-iii.pdf accessed on December 6th, 2018 at 8.27 PM

[55] *Types of patents: Everything You Need to Know,* https://www.upcounsel.com/types-of-patents accessed on December 7th, 2018 at 3.46 PM

Processes refer to any acts or methods of doing something, usually involving industrial or technical processes. Compositions of matter are basically chemical compositions, which can include a mixture of ingredients or new chemical compounds. Machines are included the things that are generally defined as a machine, such as a computer, while manufacturers are defined as goods that are manufactured or made.[56] Utility patents are protected last for 20 years. For instance, the hula-hoop serves as one of the most iconic products with a utility patent. The patent protects its unique purpose.

b. Design patents: A design patent covers how a product looks. It has nothing to do with the product's usefulness, but you can only get a design patent for a useful product or process. In order to obtain this type of patent protection, the design must be inseparable from the object. While the object and its design must be inseparable, a design patent with only protects the object's appearance. In order to protect the functional or structural features of an object, a person must also file for a utility patent.[57] Design patents are defending for 14 years. For instance, Apple has gotten patents for many of its products. For instance, the company has filed design patents for its unique iPhone.

c. Plant patents: If you are created a new species of plant, a plant patent prevents other people or companies from breeding it. A few

[56] *Type of Patents,* https://smallbusiness.findlaw.com/intellectual-property/types-of-patents.html accessed on December 7th, 2018, at 3.50 PM

[57] *Ibid*

requirements to obtain this type of patent are that the plant is not a tuber-propagated plant (i.e. an Irish potato), the plant is not found in an uncultivated state, and the plant can be asexually reproduced. Asexual reproduction means that instead of being reproduced with seed, the plant is reproduced by grafting or cutting the plant. Plant patents are required asexual reproduction because it is proof that the patent applicant can reproduce the plant.[58] Like utility patents, they last for 20 years. For instance, several variations of the poinsettia plant have get patents.

Based on the three types of the patent, it can be concluded that the patent protection is more considered to the type of the invention. Whereas, the meaning of the invention is the idea from the inventor realizes into an activity specifically in the matter of technology. It can be consist of the product or the process or improvement and development of the product or the process.[59] According to that definition, it can be concluded that the patent based on the invention is related to the process and product. However, the understanding of the patenting process can expedite the granting of a patent, decreasing legal costs, and increasing the commercial value of the invention.[60] Process patents are the patents granted to the process, while product patents are patents granted to the products.

[58] *Ibid*

[59] Endang Purwaningsih, *Seri Hukum Hak Kekayaan Intelektual Hukum Paten,Op.Cit* p.2

[60] Jeffrey I. Auerbach, *Patent Law Principle & Strategies,* http://euro.ecom.cmu.edu/program/law/08-732/Patents/PatentLawPrinciples.pdf accessed on December 7th, 2018 at 4.41 PM

According to literature, there are several types of patent currently, including:[61]

a. Independent patent, it means the patent that not depends on other patents.
b. Patent associated with the other patent (dependent patent). The relationship of the patent can occur if there is relationship between the ordinary license and the compulsory license with the other patent. In addition, both of patents have relation to each other. If the two patents are in the same field, the settlement is attempted by providing mutual licenses or cross-licenses.
c. Patent of addition or patent of improvement means the patent as an improvement or addition from to the original findings. If it is viewed in terms of the patent principal, these two types of patents are the only complementary so-called patent of accessory.
d. Patent of importation patent of revalidation, this type of patent has the specificity characteristic because it has been known abroad and the country which granted the patent only through the confirmation, strengthen, or ratification for the purpose to the applicant the patent in the territory of that country.

[61] *Pembahasan Umum Tentang Hak Paten Menurut Undang Undang Nomor 14 Tahun 2001*, http://bpatp.litbang.pertanian.go.id/ind/images/stories/pdf/hakpaten.pdf accessed on December 7th, 2018, at 5.37 PM

Moreover, the patent protection is given the right of the inventor for his invention through an exclusive right. However, the kind patents based on the right are consisting of moral right and economic right. Moral right means the rights of the creator included the prohibition for people to change the name of invention. Whereas, the moral right cannot be transferred to other people because moral rights are the kind of personal right. In another hand, economic right is the right to get the economic benefit from intellectual property. According to several scholars, the basic reason to grant the right is because of three philosophical basics. The three philosophical basic is consist of the reward theory, recovery theory, and incentive theory. Based on those theories are stated the creator or the inventor in the process have a huge sacrifice. For this reason, they must get the reward and compensation of their sacrifice and ability.[62] The kind of payment as the reward and compensation knows with economic right.

Especially in Indonesia, patent is consist of two types, namely patent and simple patent. Patent is exclusive rights granted by the state to inventors for the results of their inventions in the field of technology which for a certain period of time carry out their own inventions or give their approval for other parties to implement the inventions. A simple patent is an exclusive right granted by the state to the inventor for the results of his invention in the form of new product or tool, which has practical value due

[62] Budi Agus Riswandi and Shabhi Mahmashani, *Dinamika Hak Kekayaan Intelektual dalam Masyarakat Kreatif,* 1st edition, Total Media, Yogyakarta, 2009, p.136

to its shape, configuration, construction or component.[63] In addition, the object of a simple patent is just limited to the tangible object, not in the matter of intangible.[64] The object of the simple patent is not including to the process, using, composition and the product by the process.[65] Furthermore, another differentiation between the patent and simple patent is related to the time period. The protection period for ordinary patents is 20 years, while a simple patent is 10 years. In this matter, Patents cannot be extended. Furthermore, patent may expire if for three consecutive years the patent holder does not pay maintenance fees, the patent is declared null and void from the date of the end of the payment obligation for the third year (1-6).[66]

4. Patent Protection System

Generally, the patent system gives the exclusive right in the form of patent to someone who has already published a new invention with the compensation of the legal protection during the period of time which is already determined with several requirements. Thereby, it covers the opportunity for the third parties to utilize the invention which is already published. Patent system also has the purpose to improve the invention and

[63] Karna Wijaya, *Pemahaman Patent,* https://pse.ugm.ac.id/389/ accessed on November 30th, 2018, at 4.54 PM

[64] Endang Purwaningsih, *Seri Hukum Hak Kekayaan Intelektual Hukum Paten, Op.Cit,*p.26

[65] *Intellectual Property Right,* https://www.academia.edu/9497477/HAK_KEKAYAAN_INTELEKTUAL_Intellectual_Property_Right accessed on November 30th, 2018 at 5.05 PM

[66] Karna Wijaya, *Op.Cit*

give the contribution for the industry development by looking for harmonization between the people who already obtained the patent and the third parties related to the patent right.[67]

There are two systems to protect the patent system such as the first-to-file system and first-to-invent system. Under the first-to-file rule, because the priority of invention must be established by filing for a patent. This points to two types of pure-strategy equilibria: one in which both firms file for a patent immediately, and one in which both are improving the invention. In another side, first-to-invent means when both firms apply for a patent, priority is determined through interferences. As noted there, both firms equally share the cost of an interferences hearing. For the next two subsections, it will assume that the inventor files for a patent after the improvement process. First-to-invent is the priority system using by the American Patent Law. [68]

In other words, the America Patent Law is using the system of first-to-invent concern to the inventor who diligently worked on reducing his or her invention to practice by building a prototype and/or filing a patent application is entitled to the date of conception as the "priority date," as long as that inventor did not abandon, suppress or conceal the invention. Under these circumstances, the first inventor to understand the invention is

[67] Endang Purwaningsih, *Seri Hukum Hak Kekayaan Intelektual Hukum Paten, Op.Cit* p.5

[68] Kaz Miyagiwa, *First-to-Invent Versus First-to-File: Invention, and International Patent Law Harmonization,* http://economics.emory.edu/home/documents/workingpapers/miyagiwa_09_04_paper.pdf accessed on December 7th, 2018, at 1.51 PM

entitled to a patent. However, if two inventors file patent applications on the same invention, there may be an interference hearing before the Board of Appeals and Interferences at the US Patent Office to determine who conceived of the invention first, and whether the inventors have been diligent in reducing their inventions to practice. This is an expensive and involved procedure. This is, in essence, how the First-to-Invent patent system works. United States and Philippines are the two countries in the world whose patent systems are based on the First-to-Invent regime. The rest of the world uses the First-to-File system, which gives priority to the inventor as the first files a patent application, regardless of the date of conception.[69]

Among the advantages of the US first-to-invent system is that it rewards the first inventor, not the winner of the race to the Patent Office. In another side, the disadvantage of the first-to-invent system is a costly and lengthy interference proceeding to determine who of the two inventors conceived of the invention first. Indeed, the expense of fighting patent interference may prove prohibitive for a small inventor, leading to abandonment of the patent application. It is not inconceivable that an inventor who was first to conceive of an invention and first-to-file a patent application may not receive a patent due to the prohibitive cost of proving the date of conception. However, such situations are rare and

[69] General Patent Corporation, *First-to-File vs First-to-Invent,* http://www.generalpatent.com/articles/first-file-vs-first-invent accessed on December 7th, 2018, at 2.08 PM

interference proceedings are infrequent. Most patent attorneys involved in patent prosecution go through their entire professional career without ever representing a client in an interference dispute.[70]

In another side, the theoretical basis of the first-to-file system stems from the contract theory of patents. Under this theory, a patent is a contract between an inventor and the public which grants the inventor a public franchise (i.e., a patent monopoly) in exchange for public disclosure of the invention. If a patent is a *quid pro quo* (something for something or in other word exchange something[71]) for public disclosure of the invention, then it is reasonable to reward with a patent monopoly the first inventor to disclose the invention to the public. A practical advantage of the first-to-file systems is its utter simplicity. There are no interference disputes whoever get the earliest postmark stamp on the patent application gets the patent. Another advantage of the First-to-File system is that it eliminates so-called "secret prior art," which are inventions for which patent applications have not yet been filed and therefore cannot be found through a prior art search. If they are filed, such patent applications could preclude other inventors from getting a patent (if the date of conception by the first inventor is earlier than the date of conception by the second inventor.) This happens, and the advantage is related to marginal value.[72]

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[70] *Ibid*

[71] Business Dictionary, http://www.businessdictionary.com/definition/quid-pro-quo.html accessed on December 7th, 2019 at 3.00 PM

[72] General Patent Corporation, *Loc.Cit*

Whereas, most of the countries was adopted the patent system of first-to-file such as Indonesia and India. Both of countries was adopted the principle regarding the first-to-file system is employed, in which among persons having filed for the same inventions, first one is granted a patent. Therefore, a patent application should be filed properly after conceiving the invention. In addition, it is advisable to apply for a patent as soon as the inventor's idea of the nature of the invention has taken a definite shape. They need not wait until their inventions are fully developed for commercial working before applying for patents. The patents act provides for a mechanism by which the inventor may secure his right to be identified with the invention.[73]

Overall, the patent protection system are consist of two systems such as first-to-file and first-to-invent. First-to-file is the system that more priority to inventor who as the first fulfill the requirement to grant the patent and publish his or her invention to the public. In another side, first-to-invent is preferred to grant the patent protection for the inventor who as the first who found and understand the invention. In the practice, almost all of the states was adopted the system of first-to-file, only United States and Philippine which is adopted the system of first-to-invent and the rest of the states was adopted first-to-file.

[73] *General Principles Of Patent Law, Loc.Cit*

5. Time Period of Patent

Paris Convention as the one of legal basis did not explain the exact time or period of time to protect the invention. It only describes based on each of the countries and not harm or loss to the right as mention in Article 4 paragraph D point 4, it is stated that:

> *"No other formalities may be required for the declaration of priority at the time of filing the application. Each country of the Union shall determine the consequences of failure to comply with the formalities prescribed by this Article, but such consequences shall in no case go beyond the loss of the right of priority."*

In another hand, the TRIPs Agreement already gives the exact time period of the patent protection as mention in Article 33 TRIPs Agreement, it is stated that:

> *"The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."*

In the national law, Article 33 TRIPs Agreement is become the legal basis to determine the time period of patent protection. For instance in Article 22 and 23 Law Number 13 of 2016 on Patent, it is stated that:

1. The patent is granted for a period of 20 (twenty) years from the Filing Date.
2. A simple patent is granted for a period of 10 (ten) years from the date of registration

The time period for patent protection is given since the date of reception and the time period for patent protection cannot be extended. This basic consideration of the government to grant the simple patent

shorter that patent because in general, the product or tool which is protected obtainable shorter. Another reason, the procedure in the simple patent is more simple and cheap. Based on that consideration, the time duration is protected for the simple protection in 10 years felt enough to obtain the economic benefit.[74]

In another state, India as one of the countries who was implemented the patent protection also decide the time period of the protection in the duration of 20 years as stated in Section 53 India Patent Act, it was explained that:

> *The term of patent.—(1) Subject to the provisions of this Act, the term of every patent granted, after the commencement of the Patents (Amendment) Act, 2002, and the term of every patent which has not expired and has not ceased to have effect, on the date of such commencement, under this Act, shall be twenty years from the date of filing of the application for the patent.*
>
> *Explanation.—For the purposes of this subsection, the term of the patent in case of International applications filed under the Patent Cooperation Treaty designating India, shall be twenty years from the international filing date accorded under the Patent Cooperation Treaty.*

6. Patent Infringement

According to Black Law Dictionary defines patent infringement as follows:[75]

> *"the unauthorized making, using, offering to sell, selling, or importing into the United States of any patented invention" USCA 271(a)- Also termed infringement of patent*
>
> > *"In determining whether an accused device or composition infringes a valid patent, resort must be had in the first instance to the words of the claim. If accused matter falls*

[74] Khoirul Hidayah, *Op.Cit,* p.76
[75] Brayn A. Garner, *Op. Cit,* p.901

clearly within the claim, infringement is made out and that is the end of it" Graver Tank & Mfg Co. c. Linde Air Prods. Co.

In the practice, the patent protection already gives the protection to the inventor from the using his or her invention or creation that has the characters from the originality of using the invention based on the permission or the right from patent holder. The using of the invention is included the announcement and duplication also the transfer of the creation. However, the using of the creation by other people is included announce, duplicate and transfer for the commercial interest without the permission of the creator, it is categorized as the infringement.[76] As mentioned by World Intellectual Organization Property (WIPO), it is stated that:[77]

> *"An infringement of the exclusive right of a patent owner involves unauthorized exploitation of the patented invention by a third party. The making of the invention is in particular, and its development for industrial application, usually involves the applicant and the future owner of the patent for invention. The patent owner thus wishes to recover this expense of the exploited through patented invention, is in particular through the sale of products that incorporate the invention."*

In general, patent infringement defines as the action for making, using, selling or offering an invention without patent holder consent in the state where the patent was protected and register. In other words, the patent infringement is the violence of limitation of the territory of the

[76] Budi Agus Riswandi and Shabhi Mahmashani, *Op. Cit,* p.135

[77] World Intellectual Property Organization, *Fields of Intellectual Property Protection,* https://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch2.pdf accessed on December 2nd, 2018 at 2.00 PM

patent holder which is described in the claim of patent invention. In America, there are two types of Infringement such as direct and indirect infringement. Direct infringement is the right conducted by the patent holder to avoid the other parties to make, use, offer or sell, and import the invention result. In another side, indirect infringement is the someone action that encourages other people to conduct patent infringement even though he never makes, uses or sells the patent invention. Besides that, the act of making and selling an item or component specifically intended to be attached or adapted into a patent invention.[78]

Furthermore, there are several ways in which the infringement of patent rights might arise. The first, there is the situation where a patent is deliberately infringed by the third party without any attempt to avoid the infringement. This will be straight either copying of the invention or otherwise involving minor variations or modifications thereof. This form of infringement may occur because the third party is unscrupulous, or because the parties have been advised by his patent agent that the patent in one question or more claims thereof, it is invalid. With this form of infringement, there is generally no argument related to whether or not there is infringement. If all of the features of the patented invention have been copied, then there must be infringement, and the only matter to be

[78] Arianne Astrinia and Brian Amy Prasetyo, *Perbandingan Konsep Pelanggaran Patent di Indonesia dan Amerika Serikat: Studi Kasus Pelanggaran Patent Obat,* FH UI, Depok, 2014 p. 5

resolved is whether the claims of the patent are valid. The second situation which arises where the infringement is deliberate, but some attempt has been made to avoid the appearance of infringement. It frequently happens that once an invention is disclosed either by the sale of the product incorporating the invention, in a published patent document, or in some other publication the third parties are given ideas. The publication generally outlines the problem and shows a way of solving it. Third parties then may endeavor to design an alternative to do the same thing. While third parties may try to design around the patent, whilst the basic idea is still use the basic idea from the inventor, the result does not always clearly fall outside the scope of the claims of the patent. This is probably the most common form of infringement faced by patent owners and it gives rise to the most litigation. The last situation that arises in the case of accidental infringement. As soon as a patent owner comes across something which embodies his idea he naturally feels that his invention is being copied. This is not necessarily since there are many people working to solve a particular problem at the same time. For example, research departments of different large organizations may all be working on a similar problem. Similarly, there may be several companies who have been asked to tender for a contract to solve a particular problem or to achieve a certain result, and in so doing may come up with similar ideas to that which may have been involved in the patented invention. Thus, although the

patent owner may feel that his invention has been copied, the third party has, in fact, arrived at a similar if not identical solution via a different route.[79]

In addition, there are several elements to prove the infringement of the patent such as; first, the carrying out of a prohibited act. The second element is the prohibited act must have been done after the publication of the patent application, or the issuance of the patent where no early publication occurs. Third, the prohibited act must have been done in the country where the patent has been granted. The last, the prohibited must be in relation to a product or process falling within the scope of a claim of the patent. [80]

To concluded, the patent infringement can be done through the several acts such as making, using, selling, distributing, producing, importing or offering the invention which already gets the patent protection conducted by person or cooperation either directly or indirectly without permission of patent holder.

7. Patent Dispute Settlement

Related to the patent infringement, the patent holder usually bring the case related to patent infringement to the court. Thereby, the TRIPs

[79] World Intellectual Property Organization, *World Intellectual Property Organization: Intellectual Property Handbook*, *Op.Cit* p. 29

[80] *Ibid*

Agreement already provide the process as stated in Article 34 TRIPs Agreement, as follows:

> 1) *For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:*
>   a. *if the product obtained by the patented process is new;*
>   b. *if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.*
> 2) *Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.*
> 3) *In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.*

In addition, the Article 41 until 49 regarding enforcement of Intellectual Property Right to settle the dispute can be done through the administrative procedure, civil procedure, or criminal procedure as stated in article 61. Moreover, the provision in TRIPs Agreement also provide related to injunctions, damages and temporary action. In addition, the Article 64 TRIPs Agreement stated that to settle the dispute may apply to consultation and to settle dispute under the Article XXII and XXIII GATT 1994 clarified with the Understanding on Rules and Procedures Governing

the Settlement of Dispute as for the consultation forum and dispute resolution according to TRIPs Agreement.[81]

Related to the procedure, actually TRIPs Agreement did not give strict regulation regarding procedure for dispute settlement in the matter of patent infringement. However, as mentioned in Article 34 TRIPs Agreement, the subject matter of patent can sue to the judicial authority if there is patent infringement with the prove related to the process has similarities or differences with the invention that already granted by the patent protection. Moreover, the dispute settlement regarding the patent infringement in every state has different each of state. For instance, in Indonesia, the dispute settlement sued to the commercial court. In addition, Indonsia Patent Law the evidence is stated in Article 145 paragraph 1 Law Number 13 of 2016, consist of:

> *in examining a claim against a patented process, the obligation of proof is charged to the defendant if:*
>
> *a. the product produced through the process given the patent is a new product; or*
>
> *b. the product is considered thought the resulting process from patented process, even though there is an effort has been made to prove, the patent holder still cannot determine the process used to produce the intended product.*

In the practice, Indonesia gives an opportunity to the parties who want settle the dispute in the matter of administrative procedure, litigation process whether through the criminal or civil, and also through Alternative

[81] Endang Purwaningsih, *Seri Hukum Hak Kekayaan Intelektual Hukum Paten, Op.Cit*, p.27

Dispute Resolution (ADR). Alternative Dispute Resolution according to Harahap can take the role if based on business etic because the alternative dispute resolution is not an ordinary court that has the forcing power.[82]

In other sides, India has a different way to settle the dispute. Under the Indian Patents Act 1970, the District Court is the court of the first instance for patent infringement actions. If the defendant seeks to challenge the validity of the patent during an infringement action, the action must be transferred to the High Court. However, the High Courts of Delhi, Bombay, Calcutta and Madras exercise original jurisdiction for patent infringement actions that are within their pecuniary jurisdiction, as prescribed under the relevant rules. It means that an infringement action can be brought directly before these High Courts provided that the applicable pecuniary thresholds are satisfied.[83]

8. Patent According to International and National Perspective

Generally, the patent right has implemented by every state should be in the principle of non-discrimination. After the requirement already fulfills then the invention will get protection right given by the government for the patent holder. The kind of the right called as the exclusive right. In

[82] Endang Purwaningsih, *Seri Hukum Hak Kekayaan Intelektual Hukum Paten, Op.Cit,* p.28

[83] Pravin Anand and Aassish Somasi, *Patent Litigation in India: Overview,* https://uk.practicallaw.thomsonreuters.com/4-621-1358?transitionType=Default&contextData=(sc.Default)&firstPage=true&comp=pluk&bhcp=1 accessed on December 3rd, 2018, at 3.43 PM

international level, patent regulates under TRIPs Agreement the protection of the invention through exclusive right has the purpose for the protection of the patent holder and the invention. However, the exclusive right of the patent protection is lead to the monopoly right. The implication of the right it makes the damage to the public interest especially in the developing countries because the exclusive right makes the high price of the invention that makes the developing countries are difficult to access the invention of technology. TRIPs Agreement as the one of the legal basis of patent law does not only provide the protection of the invention but also provide the provision regarding the flexibility of the patent to implement the basic principle regarding public interest.

Almost all of the state members have implemented the patent for the purpose of public interest. In international level, the consideration related to the public interest was generally regulated under Article 7 TRIPs Agreement, it was determined that:[84]

> *The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to 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.*

In national level, several countries especially the state member implement the patent law in line with the provision in the TRIPs

[84] Winner Sitorus, "Kepentingan Umum dalam Perlindungan Paten", *Journal Hukum,* Vol. 29 No 1, Fakultas Hukum Universitas Hasanuddin, 2014 p.42

Agreement. In the practice, each of the states has a different treatment to implement the patent law because the provision in Article 1 TRIPs Agreement stated the state shall be free to determine the appropriate method and implement the provision with own legal system and the practice. It means the provision regarding patent protection is based on each national system. Even though the state has implemented the patent protection by their national law, but most of the states implement the patent protection with the same principal and purpose for public interest as in line with the basic provision in TRIPs Agreement.

According to Indonesia Law as stated in Article 1 Law Number 13 of 2016 on patent, it defines: [85]

> *"Patent is the exclusive right which is given to the state because of the result of the invention in the matter of the technology for certain time to implement his or her invention to other parties."*

In another side, India Patent Act, 1970 amended lastly in act number 2005 defines patent for any invention granted under this act. In addition, the term of patent is also known as 'new invention'. The explanation is, as follows: [86]

> *"Any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification."*

[85] Indonesia, Law Number 13 of 2016 on Patent. Article 1 paragraph 1
[86] India Patent Act,1970 *amended by patent*(Amendment)Act, 2005

Overall, the concept of patent in Indonesia and India is the same. Patent accoding to both countries is regarding the protection of the invention created by the patent holder. The kind of the protection is exlusive right related to give or not to give permission to use the invention. Furthermore, the patent is related to the transfer the right from patent holder to another with certain way such as government use, license or compulsory license.

B. The Concept of Flexibility

1. Definition of Flexibility

The term of flexibility comes from the word of flexible, according to Cambridge Dictionary provide the definition of flexible as follows:[87]

> *"flexible is able to change or be changed easily according to the situation"*

In addition, Merriam-Webster gives the meaning regarding the flexible in the words:[88]

> *"flexible characterized by a ready capability to adapt to new, different, or charging requirement"*

[87] *Cambridge Dictionary*, https://dictionary.cambridge.org/dictionary/english/flexible accessed on November 30th, 2018, at 9.02 PM

[88] *Merriam-Webster,* https://www.merriam-webster.com/dictionary/flexibility accessed on November 30th,2018, at 9.05 PM

In addition, the term of flexibility of patent has closed meaning to the exhaustion doctrine, as stated in Black Law Dictionary explains the meaning of patent-exhaustion doctrine defines flexibility as follow:[89]

> *"The rule that the unconditioned sale of a patented article ends the patentee's monopoly right to control its use. That the control may still be exercised by the limitation of contract or license, as long as it does not amount to anticompetitive misuse."*

Furthermore, TRIPs as one of the legal basis of patent protection is not explained yet regarding the term of flexibility. However, there is a provision regarding exceptions to right confer which is stated the state member may provide the limited exception to the exclusive right which is as the kind to flexible the patent protection. Whereas, the definition of exception according to Cambridge Dictionary:[90]

> *"Someone or something that is not included in a rule, group or list or that does not behave in an expected way"*

In another side, Oxford Dictionary provides the definition of the exception, it is stated that:[91]

> *"A person or thing that is excluded from a general statement or does not follow a rule"*

In addition, the Black Law Dictionary defines the meaning of limit as follow:[92]

> *"A restriction of restraint, a boundary or defining the line, the extent of power, right or authority."*

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[89] Brayn A. Garner, *Op.Cit.* p.1304

[90] *Cambridge Dictionary,* https://dictionary.cambridge.org/dictionary/english/exception accessed on November 30th, 2018, at 8.53 PM

[91] *Oxford living Dictionaries,* https://en.oxforddictionaries.com/definition/exception accessed on November 30th, 2018, at 8.55 PM

[92] Brayn A. Garner, *Op.Cit,* p.1069

According to the Oxford Dictionary explains the definition of a limit as follows:[93]

> *"a point or level beyond which something does not or may not extend or pass"*

Based on several definitions above, it can be concluded that the flexibility of the patent is the kind of the option to except and limit the right by the patent protection (exclusive right). In addition, the flexibility of the patent has a special characteristic, which is different to other common provision, and it permitted based on law.

2. Flexibility Based on Law

In international level, flexibility as the kind exception and limitation as stated generally in Article 3 TRIPs Agreement as follows:

1. *Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.*
2. *Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such*

[93] *Oxford Living Dictionaries,* https://en.oxforddictionaries.com/definition/limit accessed on November 30th, 2018, at 8.58 PM

practices are not applied in a manner which would constitute a disguised restriction on trade.

Based on Article 3 regarding National Treatment the state member may except the provision if it is related to secure the law and regulation that contradict with TRIPs Agreement. the In addition, there are two basic principles provided in Article 8 TRIPs Agreement which is must be considered by the state member, as follows:

a. *Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.*
b. *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 which unreasonably restrain trade or adversely affect the international transfer of technology.*

However, the principle in the TRIPs Agreement still has unclear because there is no explanation regarding the meaning or scope of the public interest includes the health of the society. Hereby, the Doha Declaration which consists 8 paragraphs provided the interpretation for the Article 7 and 8 TRIPs Agreement. Generally, the Doha Declaration stated that the WTO member has the right to interpreted provision to defend the interest of society interest which is regulated in the TRIPs Agreement, which is interpreted by the Doha Declaration paragraph 4 stated: [94]

> *"We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.*

[94] Tomi Suryo Utomo, *Deklarasi Doha Dalam Perspektif Akses Obat Murah dan Terjangkau: Sebuah Pelengkap Perjanjian TRIPS,* Universitas Janabadra, Yogyakarta p.124

> *Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.*
> *In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."*

As mention in paragraph 4 Doha Declaration, the basic reason for the flexible the exclusive right has the reason for the protect public health and access to medicine. So that, if the invention related to the public health such as access for the medicine, there are possibility to implement the exception and limitation for the third parties using the invention without need the permission of the patent holder.

C. Flexibility on Patent Law

Whereas, according to Article 27 paragraph 2 gives more specific provision regarding the exception and limitation regarding specify in patent protection which has stated in Article 27 paragraph 2 on TRIPs Agreement the state members could exclude the patent right as follow:

> *"Members may exclude from patentability invention, the prevention within their territory of the commercial exploitation of which is necessary to protect 'ordre public' or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."*

Based on the Article 27 in the TRIPs Agreement already clear explain, there is a possibility to except the patent right as long as has the reason to protect public order whether for human, animal, or plant. The

government can decline to issue the patent for an invention of the sales needs for the reasons of public order or morality they can also exclude diagnostics therapeutic and surgical methods, plants and animal and biological process from patent protection.[95] The several objects could be excluded from patentability explained more deeply in Article 27 paragraphs 3 consists of:

> *Members may also exclude from patentability:*
> a. *Diagnostic, therapeutic and surgical methods for the treatment of human or animals;*
> b. *Plants and animals other than micro-organisms, and essentially biological processes for the production of plant or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by effective 'sui generis' system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.*

Moreover, the limitation and exception have permitted according to Article 30 TRIPs Agreement, it is stated that:

> *"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."*

Overall, the TRIPs Agreement allows "limited exception" to the exclusive right conferred by the patent. When implementing the flexibility of patent, it must consider to the reason for protect public order whether for human, animal, or plant. If the invention is related to the human, animal,

[95] World Trade Organization, *Intellectual Property: Protection and Enforcement, Loc.Cit*

or plant, it is possible to flexibile the exclusive right to prevent monopoly right.

D. Criteria of Flexibility

The term "flexibilities" means, there are different options through TRIPs obligations which can be transposed into national law so that national interests are accommodated and the TRIPs provisions also principles are complied with. This definition would effectively delimit the scope of the concept through the following elements:[96]

i. it highlights the idea of various options for means of the implementation;

ii. it refers to the legislative process of the implementation, reflecting which the first step to get the advantage of given flexibility consists in incorporating it into the national law;

iii. it refers to the reason for flexibilities, which is to accommodate national interest; and

iv. it reflects which given flexibility needs to be compatible with the provisions and principles of the treaty."

Moreover, the limitation and exception have permitted according to Article 30 TRIPs Agreement, it is stated that:

> *"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent*

[96] Hans Georg Bartels, *Loc.Cit*

owner, taking account of the legitimate interests of third parties."

Article 30 TRIPs allows "limited exception" to the exclusive right conferred by the patent. Three requirements must be met to invoke this article. First. The exception must be limited. Second, it must be unreasonably conflicting with a normal exploitation of the patent. The last, it must not "unreasonably prejudice the legitimate expectations of patent owner." [97]

In addition, the important flexibility has allowed by the World Trade Organization (WTO) member to determine what it means by 'invention', a concept that is not defined in the TRIPs Agreement. In fact, there is significant diversity in law and practice around the nation of the invention, and there is no complain field by WTO regarding the definition of the invention. In particular, the national law before entering into the analysis of compliance with the patentability requirements. [98]

The World Health Organization (WHO) Commission on Intellectual Property Right, Innovation and public health also noted that: [99]

> *"The TRIPs Agreement allows countries a considerable degree of freedom in how they implement their patent law, subject to meeting its minimum standard, including the criteria for patentability laid down in TRIPs. Since the benefit and cost of the patent are unevenly distributed across countries, according to their level of development and scientific and technological capacity, countries may devise their*

[97] Mitsuo Matsusshita, Thomas J. Schoenbaum and Petros C. Mavroidis, *Op.Cit* p. 727

[98] Carlos M Correa, *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patent from a Public Health Perspective*, United Nation Development Programmer, p.18

[99] WHO Commission on Intellectual Property Rights, *Innovation and Public Health,* quoted from Charlos M Correa, *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patent from a Public Health Perspective,*United Nation Development Programmer, p. 19

patent systems to seek the best balance, in their own circumstance, between benefit and costs. Thus developing countries may determine in their own ways the definition of an invention, the criteria for judging patentability, the right conferred on the patent owner and what exception to patentability are permitted, provided these are consistent with the relevant article of TRIPs (for WTO member)"

The Doha Declaration on the TRIPs Agreement and Public Health confirmed the right of WTO member to use the TRIPS flexibilities, such as:[100]

Adopting specific guidelines in relation to the examination of the patent application for pharmaceuticals does not violate the non-discrimination clause contained in article 27.1 TRIPs Agreement. Countries that decide to develop and apply specific guidelines to ensure that the patent application relating to pharmaceuticals are rigorously examined act in conformity with the TRIPs Agreement. The Declaration on Patent Protection: Regulatory Sovereignty under TRIPs developed under the auspices of the Max Planck Institute for Innovation and Competition confirms that:

Every technology is more or less unique with regards to its exposure to market failure, its susceptibility to patent protection, and its socio-economic implication. Measures to accommodate these differences cannot be considered contrary to article 27(1) of the TRIPs Agreement. While that provision prohibits discrimination as to the field of technology, it does not prevent states from treating different situations differently. The differentiation that serves to level and actual conditions of competition across all fields of technology is not discriminatory but rather the opposite. It constitutes a necessary response to the diversity of technologies and consequently, a 'conditio sine qua non' for an intrinsically balanced system of protection of patentability, patent eligibility, and disclosure.. to the exclusion of subject matter from patentability as well as to the scope of protection.

[100] Available at www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm quoted from Charlos M Correa, *Guidelines for PharmaceuticaL Patent Examination: Examining Pharmaceutical Patent from a Public Health Perspective*, United Nation Development Programmer, p. 19

In addition, Doha Declaration in Paragraph 5 gives the explanation regarding the flexibility, it is stated that:

> *we recognize that these flexibilities include:*
>
> *a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.*
>
> *b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.*
>
> *c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.*
>
> *d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."*

Based on the paragraph in Doha Declaration, gives the explanation to the state member of WTO especially for the developing countries can implement the protection provided through the parallel import and compulsory license for the purpose of the society heartiness. In general, regarding basic requirement for flexible the patent right there is no specific requirement, because the state is free to regulated the patent as long as not contradict with general principle of TRIPs Agreement. Therefore, it is based on each of state regulation to regulate the patent also the exception and limitation of the patent itself.

E. Flexibility in Several Countries (Indonesia and India)

The flexibility of exclusive right on the patent protection has implemented in every state member. In order to serve public interest, many countries highlighted the purpose of patent law and the necessity of providing an appropriate balance of patent rights, considering the rights of patent holders, the interests of users of the patented technology and the public at large to maximize the social benefits. In the national or regional level, the exclusions from patentable subject matter provided in national legislation vary significantly. Nevertheless, certain categories of subject matter are considered to be excluded from patentability in many countries, it includes:[101]

a. inventions the exploitation of which is against *ordre public* or morality;
b. diagnostic, therapeutic and surgical methods for the treatment of humans and animals;
c. plant and animal varieties;
d. plants and animals other than micro-organisms;
e. essentially biological processes for the production of plants and animals;
f. inventions affecting national security.

[101] World Intellectual Property Organization (WIPO), *Exclusion From Patentable Subject Matter and Exception and Limitations to the Rights,* (Geneva; WIPO Publication SCP/13/3, March 2009) Thirteenth Session, p. 3

However, the implementation regarding the scope to except and limit the exclusive right has different each other. In another side, most countries have applied the scope of exception where the experimental use and/or research exception is contained in statutory laws, the relevant provision states that the right conferred by a patent does not extend to, for example, activities for experimental or research purposes, acts for scientific experiment or scientific research, act for scientific research or experiment, acts for experimental purposes, acts for scientific research purposes, acts carried out for experimental purposes in the course of scientific and technical research, or using inventions for the purposes of evaluation, analysis, research, teaching, testing, and trial production. [102]

In some Member States, their national laws explicitly require that the research exceptions shall not violate the legitimate interests of the patent holder by stating that, for example, the exception shall not "conflict with a normal exploitation of the patent" and shall not "unreasonably prejudice the legitimate interests of the patent holder". Similarly, the Indonesia Patent Law is stated that the patent rights do not extend to the use of a patent for the purposes of education, research, experiment, or analysis "as long as it does not harm the normal interest of the patent holder".[103] As mention in Article 9 Law Number 13 of 2016 on Patent, the invention which not categorizes as the patent consists of:

[102] World Intellectual Property Organization (WIPO), *Exception and Limitation to Patent Right: Experimental Use and/or Scientific Research,* (Geneva; WIPO Publication SCP/20/4, January 2014) Twentieth Session, p. 3

[103] *Ibid* p.4

a. *the process or product that announce, use or implement it is contrary to regulations, religion, public order, or decency;*
b. *methods of examination, treatment, medical, and/or surgery applied to human and/or animals;*
c. *theories and methods on the field of science and mathematics;*
d. *living things, except microorganism; or*
e. *biological processes that are essential for producing plants or animals, except for non-biological processes or microbiological processes.*

In another side, the exception and limitation of the right in India consist of:[104]

a. Importation or manufacture of articles and uses of processes by goverment or on behalf of the government for its own use;
b. Importation of medicines and drugs by the government for its own use or for distribution in dispensaries, hospitals or other medical institutions maintained by, on behalf of or specified by the government;
c. Using for purposes merely of experiment or research is including the imparting of instructions to pupils.

F. Legal Procedure of Compulsory License on Patent

1. Definition of Compulsory License

Generally, there are several ways to implement the flexibility of patent as the one effort to prevent the negative right which arises from the exclusive right such as parallel import, government use, bolar provision,

[104] World Intellectual Property Organization(WIPO), *Certain Aspect of National/Regional Patent Law,* 2018, https://www.wipo.int/export/sites/www/scp/en/national_laws/grace_period.pdf accessed on December 1st, 2018, at 7.57 PM

and compulsory license. Especially for the compulsory license has several definitions. According to Black Law Dictionary defines the meaning of compulsory license as:[105]

> *"A statutorily created license that allows certain people to pay royalty and use an invention without the patentee's permission"*

In another side, Business Dictionary defines the meaning of compulsory license, it was mentioned that:[106]

> "*Patent-use license granted on court orders when the patent holder fails to make use of it"*

In addition, World Trade Organization explain the compulsory licensing as follows:[107]

> *"For patents: when the authorities license companies or individuals other than the patent owner to use the rights of the patent — to make, use, sell or import a product under patent (i.e. a patented product or a product made by a patented process) — without the permission of the patent owner. Allowed under the WTO's TRIPS (intellectual property) Agreement provided certain procedures and conditions are fulfilled."*

However, under US Patent Law defines the meaning of compulsory license even in the U.S does not recognize the compulsory licenses, but the definition of compulsory license provided, it was explained that:[108]

> *"Compulsory license is a statutorily created license allowing certain people to pay a royalty and use an invention without getting the consent of the patentee."*

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[105] Brayn A. Garner, *Op. Cit,* p. 1060

[106] Business Dictionary, http://www.businessdictionary.com/definition/compulsory-license.html accessed on December 3rd, 2018, at 4.20 PM

[107] World Trade Organization, https://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm accessed on December 3rd, 2018 at 4.25 PM

[108] USLegal, https://definitions.uslegal.com/c/compulsory-license/ accessed on December 3rd, 2018, at 4.31 PM

Whereas, from several definitions above, it can be concluded that the compulsory license in the license given by the state for the certain parties to permit the people for use, make, process, utilize or offer the invention without getting the consent of the patent holder.

2. Legal Basis of Compulsory License

Compulsory license or the other use without the authorization of the right holder is the regulation introduced by the Paris Convention. Specifically, in Article 5A paragraph 2 stated every state members has the right to determine in the national law that abuse of the patent holder right. For instance, because patent holder is not doing the patent right, or he can be avoided with the grant of compulsory license to another person. However, the grant of compulsory license at least in the three years after the grant of the patent and the patent holder cannot give the legal reason regarding the cause that makes him cannot using the invention. [109] According to the Paris Convention as one of the legal basis was regulated the compulsory license in Article 5A paragraph 4, it was stated that:[110]

> *"A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non–exclusive and shall not be transferable, even in the form of the grant of a sub–license,*

[109] Muhamad Djumhana and Djubaedillah, *Op.Cit.* p.174
[110] OK. Saidin, *Loc.Cit*

except with that part of the enterprise or goodwill which exploits such license."[111]

Not only Paris Convention as the legal basis of the compulsory license in order to counter such abuses of patent right, but also Agreement on Trade Related Aspect of Intellectual Property Rights (TRIPs Agreement) gave the provision of compulsory license as the legal basis to keep a check on the use of the invention on grounds of public morality.[112]

TRIPs Agreement describes the right of the owner to enjoy, and the condition under which exception to this right is permitted. The TRIPs Agreement was permitted the government to issue "compulsory licenses" which allows a competitor to produce the product or process under license without the patent holder consent. However, it can be done under specific conditions of the setting out TRIPs Agreement to safeguard for the interest of the patent holder. [113]

Actually TRIPs Agreement does not use the term "compulsory license". However, based on Article 31 TRIPs Agreement provides the provision as one of the legal basis to exclude the patent which the patent can be used by the government without the authorization of the right holder which provides the requirement must be met when is ordering compulsory

[111] *Paris Convention for Protection of Industrial Property*, March 20,1883

[112] Amanpreet Kaur and Rekha Chaturvedi, "Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma*", Journal of Intellectual Property Right,* Vol.20, University of Delhi, India, 2015, p 280

[113] World Trade Organization, *Intellectual Property: Protection and Enforcement, Loc.Cit*

licensing. There are 12 principles stated in Article 31 TRIPs Agreement, as follows:

> *Where the law of a member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:*
>
> *a. authorization of such use shall be considered on its individual merits;*
> *b. such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a member in the case if a national emergency or other circumstances of extreme urgency or in cases of public non commercial use in situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable in the case of non commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;*
> *c. the scope and duration of such use shall be limited to the purpose for which it was authorized and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after the judicial or administrative process to be anti-competitive;*
> *d. such use shall be non-exclusive;*
> *e. such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;*
> *f. such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use;*
> *g. authorization for such use shall be liable, subject to adequate protection of the legitimate interest of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;*
> *h. the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;*
> *i. the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or another*

independent review by a distinct higher authority in that Member;

j. any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or another independent review by a distinct higher authority in that Member;

k. Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after the judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

l. where such use is authorized to permit the exploitation of a patent "the second patent" which cannot be exploited without infringing another patent "the first patent", the following additional conditions shall apply:

i. the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

ii. the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

iii. the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Issues regarding compulsory licensing in patent protection have the purposes for balancing two opposing interests; namely, the interest of inventors and technologically advanced countries and the countries which have less technologically advanced. Article 31 attempts to strike this balance. Nevertheless, many ambiguities and issue of the interpretation remain.[114] The ambiguities happen because based on Article 31 TRIPs Agreement has stated the state member can use the invention without

[114] Mitsuo Matsusshita, Thomas J. Schoenbaum and Petros C. Mavroidis, *Op.Cit* p.729-730

patent holder consent but just for several condition such as national emergency, public and non-commercial use. However, in the TRIPs Agreement the term of national emergency, public and non-commercial use is not explained in deeply regarding what is the meaning and the element to stated the condition already categorize as the national emergency, public and non-commercial use.[115] In the practice, it makes the several countries implement based on their interpretation.

A commentary notes in wide regarding the term 'public non-commercial use: [116]

> *There are many ways that the terms "public non-commercial use" may be defined in good faith. The term "public" could refer to use by a government, as opposed to the private entity. The term may refer also to the purpose of the use, that is, use for "public" benefit. A private entity could be charged with exploiting a patent for the benefit of the public. "Non-commercial use" may be defined either in relation to the nature of the transaction or in relation to the purpose of the use. Regarding the nature of the transaction, "non-commercial" may be understood as "not-for-profit" use. A commercial enterprise does not ordinarily enter the market without intending to earn a profit. Regarding the purpose of the use, "non-commercial" may refer to the supply of public institutions that are not functioning as commercial enterprises. The supply of a public hospital operating on a non-profit basis may be a "non-commercial" use of the patent.*

Even though the TRIPs Agreement has not provided a clear explanation regarding the provision in Article 31, but the impacts of this article have a lot of benefits. Meanwhile, the TRIPs Agreement is needed

[115] Budi Agus Riswandi dan M. Syamsydin,*Loc.Cit*

[116] *Resource Book on TRIPs and Development,* quoted from Shamnad Basheer, *The Compulsory Licence Regime in India: Past, Preset and Future* p.15

amendment to overcome the unclear provision. In November 2001, the Doha Declaration has fulfilled it. Basically, every state is allowed to issue compulsory licenses to produce and export the drugs to the countries which have less or no manufacturing capacity of drugs.[117] It also called as "the right to grant compulsory licenses". This mechanism is generally implemented in most of the patent laws, it is recognized as a permissible option or flexibility under the TRIPs Agreement, and it has been used by a number of WTO members in the pharmaceutical field. Compulsory licensing of pharmaceutical products is one of the examples of adjustment measures (or flexibility).[118]

The same regulation also stated in Doha Declaration on the TRIPs Agreement and Public Health that be held in the 9-14 November 2001 attend 142 state members of WTO refer to regulation regarding the compulsory licensing as stated: [119]

> *"We recognize 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."*

Doha Declaration has the purpose to clarify the ambiguity which is accrued between the state to implement the principle of society healthiness and the provisions in the TRIPs Agreement. Specifically, the ministerial

[117] Amanpreet Kaur and Rekha Chaturvedi,*Loc.Cit*

[118] World Trade Organization, *TRIPs, and Public Health,* https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm accessed on November 10, 2018, 16.25 PM

[119] Samariadi, *Op.Cit,* p.455

conference discusses the concern of the developing countries regarding the patent regulation that limited the access of the affordable medicine for the citizen in the developing state in their effort to control diseases, which affects society such as HIV/AIDS.[120]

Whereas, the unclear provision is also found in Article 31 (f) TRIPs Agreement stated the implementation of a compulsory license for the states member of World Trade Organization (WTO) only in the scope of domestic. It means the pharmaceutical product just for the domestic area, and it cannot be import and export to other countries. As a result, the states whose not have the capability to produce the medicine have the obstacle in the implementation of the compulsory license. This provision is contradicted with the main purpose in Article 31 TRIPs Agreement which gives permission to the compulsory license to overcome the negative impact of the patent protection. Until 2002, there is no clearness explanation regarding Article 31(f), because according to that article the production of the generic drugs such as for HIV/AIDS in antiretroviral (ARV) medicines cannot be exported. So for the state, which needs the HIV/AIDS medicine in their country should produce the medicine by themselves. Moreover, in 2003 Doha Declaration has established the general council decision TRIPs in 2003 regarding Implementation of Paragraph 6 of Doha Declaration on TRIPs Agreement and Public Health-General Council Decision of 30 August 2003. In that decision, the Article

[120] *Ibid* p.454

31 TRIPs Agreement, especially in paragraph (f) and (h), was erased to expand the scope of compulsory license more flexible to export the pharmaceutical product especially HIV/AIDS medicines to another country. [121]

Based on the explanation above, compulsory licensing has the negative implication to the inventor regarding breaking of the exclusive right of the patent holder. The purpose behind the breaking of the patent right is to change the terms of bargaining between the buyer and the seller. For instance, if the government is a buyer and the patent holder is a seller, and the parties fail to negotiate a reasonable price of the product, compulsory licensing provision provides for an arrangement using which the government may dilute exclusive patent right of the patent holder and license some other firm to sell the same product.

However, compulsory license is used the compensation as kind to paid the patent holder in exchange for use of his patent. Thus, compulsory licensing, by stimulating generic competition, is strengthen the bargaining position of the government resulting in lowering of prices. Even though the compulsory license is a violation of the rights of the patent holder, but this violation sometimes becomes necessary in order to improve the availability of essential products at affordable prices. It is pertinent to note that access to drugs or to deal with emergency public health situations is not the only reason for the grant of compulsory license. It can be used as a

[121] Khoirul Hidayah, *Hukum Hak Kekayaan Intelektual*, p. 83-85

policy mechanism to deal with anti-competitive practices, non-working of the patent, or other undesirable behavior of patent holders. In addition, compulsory license not only forces the patent holder to use his invention for the benefit of the society but also boosts generic industry of the country granting such license.[122]

Since several advantages from the implementation of the compulsory license especially for the developing countries, the several developing countries already implement the compulsory license in the matter of pharmaceutical product. In the case of the pharmaceutical product or drugs, TRIPs Agreement gives the opportunity to the state member regulates for the purpose of the citizen healthiness. Generally, the purpose is guaranteeing the stock and distribution, especially for the developing countries emphasize it for the public interest, the medicine or pharmaceutical products can be used without permission or consent of the patent holder. This condition related to the need of the essential medicine. In the practice, the compulsory license in the form of medicine given by the state in the emergency situation and urgent situation such as facing disaster or epidemic of illness. The compulsory license is the one of patent uses without need consent of the patent holder as stated in Article 31 TRIPs Agreement.[123]

[122] Muhammad Zaheer Abbas and Shamreeza Riaz, "Evolution of The Concept of Compulsory Licensing: A Critical Analysis of Key Developments Before and After TRIPs", *Academic Research International,* Vol 4 No.2, March 2013 p. 484

[123] Slamet Yuswanto, *Op.Cit* p.70

However, the implementation of the compulsory licensing in every state is different or not uniform because of several reasons such as experience and motivation, which is not always the same between one and another. Many developed countries leave the compulsory license with the reason difficult to justify compulsory licensing requests because there is no parameter to measure the presence or absence of the misuse or abuse. The presumption is more evolved in developed countries which the existence of the concept of compulsory licenses is increasingly considered unpopular, because is not in line with the spirit and purpose of the development of the Intellectual Property Right system. In another side, developing countries such as Indonesia, India, and other. They still apply compulsory licenses to their laws for various reasons, such as overcoming abuse of rights, the balance of rights and obligations, and others.[124]

In addition, mostly the developing countries are using the compulsory license because until now, the developing country still as the consumer for the invention in the matter of technology must adjust all form of regulations, as well as law enforcement systems to meet TRIPs standards. Another consequence that must be faced is in the form of negative impacts that arise during the adjustment for TRIPs Agreement including the increasingly expensive drug prices. By regulating the TRIPs Safeguards, it is expected the impact become decrease or minimized. In

[124] Tony Hanoraga and Niken Prasetyawati, "Lisensi Wajib Paten Sebagai Salah Satu Wujud Pembatasan Hak Ekslusif Paten", *Jurnal Sosial Humarionra*, No.2 Vol 8, November 2015, p. 162

addition, the existence of the TRIPs Safeguards will bring hope for developing and undeveloped countries to access and provide cheap and affordable medicines. [125]

3. The Procedure of Compulsory License in Indonesia

Indonesia already ratifies the Law Number 7 of 1994 on The Approval of The Formation World Trade Organization, as the consequence from the ratification of this act means Indonesia also implement all of the regulation in the matter of the Intellectual Property Right in line with the provision on the TRIPs Agreement.[126] Based on the ratification above, it means the intellectual property right especially patent protection, which is regulated in Law Number 6 of 1989 amended lastly 13 of 2016 regarding Patent based on Trade Related of Intellectual Property Rights (TRIPs) Agreement. In Indonesia, regulation gives the explanation regarding the patent is an exclusive right given by the state to the inventor for his or her invention in the matter of technology during a period of the time to implement that invention or to gives the approval for other parties to implement.

However, in Indonesia regulation is not only regulated the exclusive right but also the flexibility of patent as the one of implementation of the exception and limitation. The exception of granted

[125] Tomi Suryo Utomo, *Op.Cit,* p.271
[126] *Ibid* p.449

patent in Indonesia has the purpose to guarantee the public interest. Some exception is consist of absolute characteristic, and the rest is limited. The exception which is consist of absolute characteristic has several criteria, consist of:[127]

1. An invention related to procedure or result of the production which is the announcement and implementation contradict with the existing regulation, religious morality, public order or decency;
2. Invention regarding the theory or method in the matter of knowledge and mathematics;
3. The invention of the inspection method, treatment, medication, and/or surgery which is implemented toward human and/or animals;
4. The invention related to all of living creatures, except microorganisms;
5. The invention related to the biological process which the essential to the production of plantations or animals, except the process of non-biological or microbiological process.

In the practice, the implementation of exception and limitation can be through ways one of them is the compulsory license. The existence of compulsory license in Indonesia is very important to develop the industrial activity because cumulatively the request of patent in Indonesia still relatively few from inside the country, besides that the largest number

[127] Endang Purwaningsih, *Seri Hukum Hak Kekayaan Intelektual: Hukum Paten, Op.Cit,* p. 8

comes from abroad. It shows the ability of Indonesia to produce the invention still in the few numbers, which is affected the using of the invention especially in technology come from other countries. In this case, Indonesia must implement the compulsory license as much as possible to develop industry in Indonesia. [128]

Compulsory license is different from license. According to Gunawan Widjaja, scholar in Indonesia, explains the license as a form of the licensing to utilize an intellectual property right which has be given by the licensor to the licensee so that the recipient can carry out a form of the business activity, either in the form of technology or knowledge which can be used to produce selling produce or market certain (tangible) goods and those will be used to carry out certain service activities by using the license Intellectual Property Rights for this purpose, the licensee is required to provide counter-performance in the form of royalty payments, also known as license fees.[129]

In another side, as mention in Law Number 13 of 2016, the compulsory license is the license to implement the patent that given based on ministry decision, which has characteristic non-exclusive on the basis of the application. Generally, the basic differentiation between the license and compulsory license is related to the one who give the right. License is

[128] OK. Saidin, *Op.Cit,* p.396
[129] Tony Hanoraga and Niken Prasetyawati, *Op.Cit* p. 161

given by the patent holder consent. However, the compulsory license is given by the Ministry without patent holder consent.

Furthermore, the regulation regarding the compulsory license is regulated in Article 81 until 107 Law Number 13 of 2016 regarding the patent law. Generally, the compulsory license granted by the Ministry with several reason as stated in Article 82 paragraph 1, it is mentioned that:

> *Compulsory licenses are the license to implement the patent that given by the ministry decision base on the request with the reason:*
> a. *the patent holder does not conduct the obligation to make a product or using the process in Indonesia in line with article 19 paragraph 1 during the time 36 (thirty-six) month after granted a patent;*
> b. *patent already implement by the patent holder or get the license in the form and with the way that harms the society;*
> c. *patent as the development result that already given previously cannot be implemented by using another patent that still in the protection.*

Based on Indonesia patent act in Article 82 paragraph 1 already clear mentions the compulsory licenses only given by ministry decision based on the request with the reason stated in that article. However, the ministry granted the compulsory license only in the certain conditions as stated in Article 84 paragraph 1 as follows:

> *The compulsory license as referred to in Article 82 paragraph (1) can only be granted by the Minister if:*
> a. *the applicant or his authority can submit evidence has the ability to fully implement the Patent in full and has the facility to implement the relevant Patent as soon as possible;*
> b. *the applicant or his authority has tried to take steps in a maximum period of 12 (twelve) months to obtain a License from the Patent Holder on the basis of reasonable terms and conditions but does not obtain results; and*
> c. *The Minister in their opinion that the Patent can be implemented in Indonesia on an economical scale that is feasible and provides benefits to society.*

In addition, the implementation of the compulsory license in Indonesia must be included with the payment of royalty for the patent holder which is the number of royalty determined by the Ministry Regulation.[130] It was stated in Article 92 Law Number 13 of 2016:

1. *The acceptor of compulsory license must paid the fee or royalty to the patent holder*
2. *The provision related to the amount of royaly and the procedure of the payment as stated in paragraph 1 is regulated under Ministry Regulation.*

In addition, there is special invention that must be granted by the ministry directly such as pharmaceutical product. The pharmaceutical product as the one of exception invention that must be given the compulsory license by the ministry, which is mention in Article 93 Law Number 13 of 2015, as follows:

a. *The Minister may provide a compulsory license to produce pharmaceutical products that are given a patent in Indonesia for the treatment of diseases in humans.*
b. *The Minister may provide a compulsory license for the import of pharmaceutical products that are given patents in Indonesia but cannot be produced in Indonesia for the treatment of diseases in humans.*
c. *The Minister may provide 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 countries or undeveloped countries.*

The compulsory license usually used by Indonesia in the matter of pharmaceutical product because the healthiness of the people is the right of

[130] Much. Nurachman, *Segala Tentang HAKI Indonesia,* First Publication, Buku Biru, Jogjakarta, 2012, p. 102

every citizen especially the people who have an epidemic disease such as HIV/AIDS. It is in line with Article 100 that the implementation of the compulsory license must be used only for certain condition and purpose, it is stated that:

> *In the case of a compulsory license related to semiconductor technology, the recipient of the compulsory license can only use the compulsory license intended to:*
>
> *a. public interests that are not commercial; or*
> *b. carry out actions determined based on court decisions or decisions of related institutions stating that the implementation of the said Patent is an act of monopoly or unfair business competition.*

According to the Article 100, the compulsory license can be implemented in the matter of public interest such as the healthiness of the people. In addition, the existence of compulsory licensing in Indonesia is the kind of the option to flexible the patent protection that very important to implement in Indonesia.

For that purpose, it needs the regulation to organize the implementation for society right in the matter of the health of the citizen. The high number who has the HIV/AIDS disease makes the state necessary to fulfill the needs for essential medicines. However, the high price of the medicine becomes the obstacle to the government to fulfill the medicine access.[131] To handle this case, Indonesia implements the compulsory license to decrease the price of medicines, especially in the HIV/AIDS drugs.

[131] *Ibid* p.451

In addition, the implementation of the flexibility of patent regarding the pharmaceutical product is not only through the compulsory license but also through government use. Government use is the kind to implemented patent directly by the state or government for certain consideration as stated in Article 109 it mentions:

> *The implementation of the patent by self-government in Indonesia based on the consideration:*
> a. *related to the defense and securities of the nation; or*
> b. *very urgent needs for the society*

The kinds of situation that mention in Article 109 Indonesia Patent Law explains in the Article 110 and 111 Law Number 13 of 2016. Especially for the situation regarding urgency for the society need, it is explained in Article 111, it is stated that:

> *The Patent implementation by the Government as referred to in Article 109 paragraph (1) letter b includes:*
> a. *pharmaceutical products and/or biotechnology that are expensive and/or needed to cope with diseases that can cause a sudden number of deaths, cause significant disability, and constitute a Public Health Emergency that Raises the World (KKMMD);*
> b. *chemical products and/or biotechnology-related to agriculture needed for food security;*
> c. *veterinary drugs needed to deal with pests and/or widely spread animal diseases; and/or*
> d. *processes and/or products to cope with natural disasters and/or environmental disasters.*

Refer to the previous article, there is a specialty for the invention in the matter of pharmaceutical product because the pharmaceutical product is related to the healthiness of the citizen as the kind of basic need also basic right of every citizen that must be protected and provided by the government in the affordable price of the medicines. However, the price of

medicines is the obstacle of the government to make it more affordable because there is patent protection. Whereas, to make the price is affordable in society the government must implement the flexibility of patent in this matter is the compulsory license or government use. The special regulation in the form of the pharmaceutical product regarding medicine with the compulsory licensing is the renewal step that happens in the Intellectual Property Right, especially Patent Right.[132]

In the practice, Indonesia government has carried out its own patent in 2004 regarding epidemic prevention of HIV/AIDS in Indonesia. It is to provide the access medicine of "antiretroviral" which is at the time still protected by patent, so the government establishes President Decree Number 83 of 2004 about the Implementation of The Patent by Government Toward The Antiretroviral. At the time, the government gives the reward to the patent holder in the amount 0.5% of the selling value of the medicine of antiretrovirals. The patent holder of the medicine is Biochem Pharma INC with the time duration of patent implementation in 7 years and 9 years. Moreover, in 2007 the President Decree Number 83 of 2004 has been replaced with President Decree Number 6 of 2007. In that President Decree, the government appoints a medicine factory to produce the antiretroviral that the patent held by the foreign pharmaceutical company who resolve epidemic of HIV/AIDS. Furthermore, in 2012 the President Decree Number 6 of 2007 was replaced

[132] *Ibid* p.451

by President Regulation of Republic Indonesia Number 76 of 2012 regarding The Implementation of The Patent by The Government Towards Antiviral and Antiretroviral Medicine. [133]

4. The Procedure of Compulsory License in India

India is a hub of the big pharmaceutical industries, which is engaged in the field of the patents. According to an organization of pharmaceutical producers of India, the rank of India is third in the terms of volume of the production in pharmaceutical industry. Due to the demand of the patented product and to check the monopoly or abuse of the patent right, India patent act contains very comprehensive provisions are supportive in providing the adequate supply the need of the product and maintain public morality.[134]

India Patent Act already amended for several times, the last amendment in 1970 patent act was replaced by in 2005 because several reasons which make an influence, especially in the matter patent protection of pharmaceutical products. In the implementation of the India Patent Act 1970, the committee found that the foreigners held between 80%-90% of India patents and more than 90% of these patients were not even worked in India. This matter gives impact the price of the invention especially medicines in India rising rapidly. Therefore, the committee

[133] Khoirul Hidayah, *Hukum Hak Kekayaan Intelektual, Op.Cit* p.87
[134] Amanpreet Kaur and Rekha Chaturvedi, *Loc.Cit*

recommended that certain invention such as pharmaceutical inventions, food, and other chemical invention be granted only process patent protection. The changing of patent act significantly in the additional provision of Section 92A which provides in 1970 for compulsory licenses to enable exports of pharmaceutical products to those countries with no manufacturing capacity of their own. Unfortunately, this provision has a handicap, the provision required the exporter to obtain a compulsory license from the importing country as well. In the practice, this provision failed to cater to those situations when there was no patent in such importing country and no requirement for obtaining the compulsory license there. Therefore, the Act 2005 seeks to rectify this by adding which an exporter can resort to Section 92A where the importing country "has by notification or otherwise allowed importation of the patented pharmaceutical products from India"[135] as stated in Section 92A Indian Patent Act, it is mentioned that:

> *Compulsory license for the export of patented pharmaceutical products in certain exceptional circumstances:*
>
> 1) *Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.*
> 2) *The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory license solely for manufacture and export of the concerned pharmaceutical*

[135] Shamnad Basheer, *India's Tryst with TRIPS; The Patents (Amendment) Act, 2005,* Loc.Cit

product to such country under such terms and conditions as may be specified and published by him.

3) *The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.*

In addition, the explanation regarding the meaning of the pharmaceutical product also mention in this section as follow:

> *'Pharmaceutical products' means any patented product or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.*

Same with Indonesia, the invention related to the pharmaceutical product is neccesary to grant without any procedures. However, the procedure to grant of the compulsory license for the invention other than pharmaceutical product is mentioned on India Patent Act amended in 2005, an application for the grant of the compulsory license for the general invention other than pharmaceutical product shall be made only before making the application. The applicant has made efforts to obtain a license from the patent holder on reasonable terms and conditions, and such efforts were not been successful within a reasonable period (six months).[136] As stated in Section 84.1 the condition to grant the compulsory license under any of the following condition such as:

> *At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to*

[136] Aleksandar Ristanić, *Compulsory Licenses to Facilitate Access to Medicine: The Indian Experience,* Thesis, Faculty of Law Lund University, 2016, p.32

the Controller for grant of compulsory license on patent on any of the following grounds, namely:

a. *that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or*
b. *that the patented invention is not available to the public at a reasonably affordable price, or*
c. *that the patented invention is not worked in the territory of India.*

The India Patents Act has also attempted to explain the scope of the ground "reasonable requirements of the public". Firstly, it has noted which this requirement would cover situations when the patent holder refuses to grant a license on reasonable terms to such an extent which causes prejudice to an existing trade or industry or the development of any new trade or industry or commercial activities in general. Furthermore, it would cover various situations of the issuing licenses under unreasonable terms or situations when the patent simply fails to take steps to fulfill the demand of the patented product in an adequate manner. Lastly, the Act has clarified which the domestic production under any circumstances should not be hindered by importation. The India Patents Act has finally provided the Controller of Patents, when considering applications has to observe in particular the two main points of compulsory licenses such as patent inventions are to be worked or existed on a commercial scale in the territory of India without undue delay which is not proper, and maximum with the provision provided the interests of the patent holders are not unfairly prejudiced.[137]

[137] *Ibid*

In Addition, India Patent Act regulated the compulsory license may also be granted for any invention related to:[138]

a. For export in certain exceptional circumstance (Section 92A)
b. In case of national emergency, extreme urgency of public non-commercial use by notification of the Central Government in the official gazette (Section 92)
c. To countries having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problem (Section 92A paragraph 1)

However, there are several exception condition to grant the compulsory license. The procedure of compulsory license as stated in Section 84.1 shall not be applicable in case of the national emergency or in circumstances of the extreme urgency or in the case regarding non-commercial use or on the establishment of the ground anti-competitive practices adopted by the patentee as also stated in Section 84, it is stated that:

> *"Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on the establishment of a ground of anticompetitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application."*

[138] Harish Cander, Valbhav Choundhary and Vikas Kumar, "Current Scenario of Patent Act: Compulsory Licensing", *Indian Journal of Pharmaceutical Education and Research,* vol 47, India, 2013 p.27

The application for the grant of the compulsory license shall contain a statement mention the nature of the applicant's interest, the facts upon which the application is based and other relevant particulars. Upon consideration of an application, if the controller is satisfied that a *prima facie case* (a case in which the evidence produced is sufficient to enable a decision or verdict to be made unless the evidence is rebutted) has been made for the issue of the compulsory license, he directs the applicant to serve copies of the application upon the patentee and shall publish the application in the official journal. The patentee within two months from the date of the publication of the application may give to the controller a notice of opposition containing a statement of the grounds on which the application is opposed. The controller then notifies the applicant and gives to the applicant and the patentee an opportunity to be heard before deciding the case.[139]

While considering the application for the grant of a compulsory license, the controller shall take into account based on Section 84(6) the nature of the invention time which has elapsed since the grant of the patent measures already taken by the patentee or any licensee to make full use of the invention ability of the applicant to work the invention to the public advantage and the capacity of the applicant to undertake the risk in

[139] Vipin Mathur, Nagori, Mahendra Tiwari, "Compulsory licensing of Pharmaceutical Patent in India: A Research Study*", European Journal of Pharmaceutical and Medical Research*, ISSN 3294-3211, 2016, p.537

providing capital and working the invention, if the application was granted.

It is strengthened with Section 84(6) which is stated:

> *In considering the application filed under this section, the Controller shall take into account:*
>
> *i. the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;*
>
> *ii. the ability of the applicant to work the invention to the public advantage;*
>
> *iii. the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;*
>
> *iv. as to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:*

However, the approval of the compulsory license is not only under Section 84, but also there is a regulation regarding term and condition that must be fulfilled by the applicant during the request of the compulsory license. It is stated in Section 90 (1) as mentions:

> *In settling the terms and conditions of a license under section 84, the Controller shall endeavor to secure—*
>
> *i. that the royalty and other remuneration, if any, reserved to the patentee or another person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;*
>
> *ii. that the patented invention is worked to the fullest extent by the person to whom the license is granted and with reasonable profit to him;*
>
> *iii. that the patented articles are made available to the public at reasonably affordable prices;*
>
> *iv. that the license granted is a non-exclusive license;*
>
> *v. that the right of the licensee is non-assignable;*
>
> *vi. that the license is for the balance term of the patent unless a shorter term is consistent with the public interest;*

vii. *that the license is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product if need be in accordance with the provisions of sub-clause (iii) of clause (a) of sub-section (7) of section 84;*

viii. *that in the case of semiconductor technology, the license granted is to work the invention for public non-commercial use;*

ix. *that in case the license is granted to remedy a practice determined after the judicial or administrative process to be anti-competitive, the licensee shall be permitted to export the patented product, if need be.*

Overall, the grant of compulsory license based on India Patent Act must be considered to the remuneration of patent holder. However, the amount of royalty or remuneration is determine by the Controller based on the each case and related to the invention that want to granted the compulsory license. For instance, the case related to Catalysts and Chemicals India (West Asia) Limited v Imarial Chemical Industries Ltd (Application under ss 88.4 and 88.2 of the Indian Patent Act 1970. The controller was determined the remuneration of compulsory license in the amount of 3 percent royalty from the factory sale price of the catalyst was considered edaquate fee. [140] In addition, the compulsory license between Natco Pharma, an Indian company, for generic production related to drug Sofernib tosylate sold under the brand name Bayer Corporation's Nexavar. A drug used for the treatment of Liver and Kidney cancer. [141] Based on this

[140] Shamnad Basheer, "Compulsory Licence Regime in India; Past, Present, and Future", *Op. Cit* p.49

[141] Aayush Sharma, *Compulsory Licensing- Every Request For Compulsory License Will Not Be Granted and Special Power of The Government in Exceptional Circumstance,* http://www.mondaq.com/article.asp?article_id=576540&signup=true accessed on December 19th,2018 at 5.26 PM

case the controller decide Natco will have to pay a 6% royalty on the net sales to Bayer at the end of each quarter.

G. Intellectual Property in Islamic Law

1. Intellectual Property Right according to Islamic Perspective

The development of the technology in a state is not separated from the active role from proses of the human thinking to know and utilize anything on this earth (as a result of God's creation) through the creative and innovative studies. It cannot be denied who often conduct discovery activities are mostly carried out by Western countries which the majority of the Western countries are non-muslim. In another side, Islamic countries or the countries with a majority of muslims that mostly as developing countries only as users of the findings (technology) from the Western countries whose was produced the technology. It is affected the technology in the developing countries depends on the developed countries.[142]

In general, Islam has protection any kind of the rights given for all of the citizens, which is explained in the *nash* regarding the property right of someone. In addition, several regulations based on Al-Quran or hadist in the case of maintained the property right of someone. Basically, the main purpose of Islamic Law has protected the rights of humanity.

[142] Khoirul Hidayah, *Perlindungan Hak Paten dalam Kajian Hukum Islam dan Peran Umat Muslim dalam bidang Iptek,* Fakultas Syariah UIN Maiki, Malang, p. 86

As formulated by Al-Ghazali, he is stated the purpose of the Islamic Law to maintain five main things consist of religion, soul, mind, descent and wealth. According to positive law, the several states already implement Intellectual Property Right especially in the matter of the patent protection based on their own national regulation. In other sides, Islamic Law regulation regarding Intellectual Property Right is still not yet regulated either in the Al-Quran or in other hadist. However, the Islamic scholars try to classify this subject matter with the term of *Ijtihad*. The consequence of this classifying a case from the *Ijtihad* is that the legal entity for the case must be considered all fields, with the legal provision is not static, but dynamic. Because the case of *Ijtihad* which has been established by law not necessarily in accordance in the future, or it could be just a consideration of the place. It means, there is possibly one jurisdiction of something different from other even though at one time.

In the practice, there are two different overviews regarding the Intellectual Property Right. The first, it states that the Intellectual Property Right must be protected because has purposed of the innovation requirement and for development. If there is no protection to the innovation will make the citizen inert to find the new innovation, which is affected to the inhibition of innovation and the inhibition of the development. In addition, an inventor has also invested time, energy, money, and other resources. So that, it will appropriate that what has been

spent is valued. The second point of view, it states that intellectual property rights are actually detrimental to the public interest (public welfare) because it will further reduce public rights to private rights (individuals or companies).[143] The group who decline the protection of Intellectual Property gives example if the more expensive the invention will be affected by the high payment for the royalty to the inventor.[144]

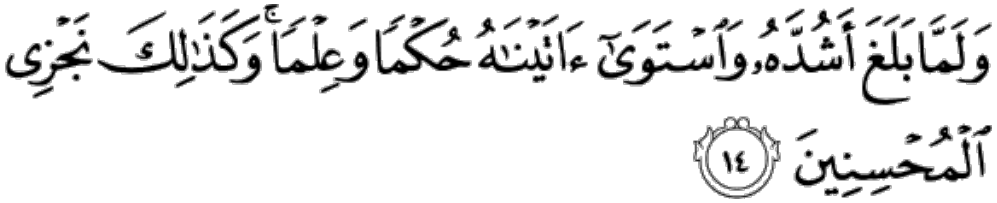
An interesting opinion can be seen in the writings of George Monbiot, in Guardian, on March 12nd 2002, entitled 'Patent Nonsense'. From his article, it is explained patent only benefits for private companies, not for the general public. It is also proven through Erich Schiff's economic history analysis, as stated it was a false statement that patents are not protected affected to the innovation will be hampered. For instance, in Switzerland and the Netherlands are two countries which in their history did not want to apply patent law, because it makes many of their industries stolen by patent right, but at the same time the development of the inventions and large companies establish from there. Some Swiss companies such as Nestle and Ciba; also Dutch companies such as Unilever and Philips are companies which are grow because of 'blessings' to steal patents or the absence of the patent rules. However, the companies are now turning lobbying to secure the patents.[145]

[143] Imam Mustofa, *Pelanggaran Hak Kekayaan Intelektual dalam Perspektif Hukum Islam* https://www.scribd.com/doc/41575867/Pelanggaran-Hak-Kekayaan-Intelektual-Dalam-Perspektif-Hukum-Islam accessed on November 17th, 2018 at 15.35 PM

[144] Budi Agus Riswandi and Shabhi Mahmashani, *Loc.Cit*

[145] *Ibid*

Even though the Intellectual Property Right is not explained in Al-Quran, the Islamic schoolars is tried to make interpretation base on several surah such as in Q.S Al-Qashas. According to Surah Al-Qashas verse 14 stated:



"And after Moses was of sufficient age and perfect reason, We gave him wisdom and knowledge. And thus We give back to those who do good."

According to Surah Al-Qashas, the word of the "give back to those" it has similar meaning to the rewards. In addition, reward in the form of intellectual property rights is the awarding of both social and economic rewards for someone who has tried to produce intellectual work. In the perspective of Islamic Law, the Intellectual Property Rights system can be justified. However, it is not permissible if the knowledge that has been obtained has purpose to enrich oneself. The knowledge that has been obtained must also be practiced and delivered to obtain benefits. In addition, Islam command to the entire human uses their sense and mind to utilize God creation as the part of worship and the kind of creativity also a creation by their mind. The patent protection is not only as the one of reward for them who wants to make an invention but also motivation to the inventor or someone will always make an innovation to fulfill the human needs and to be changed for better future.

However, the awarding of the exclusive right for the patent invention is one of reward for them who wants to think and innovate. Moreover, it is better for the human who able gives the reward as the kind of appreciate his works because Allah gives the reward to human. As mentioned in a hadith:[146]

> *"Whoever learns something the knowledge that is appropriate with that knowledge is to seek the blessing of Allah, but it turns out that to obtain worldly luxury, he will not smell heaven later on in the day of Judgment. " (H.R Ibnu majah and Ahmad)*

Based on the hadist by H.R Ibnu Majah and Ahmad explain the kind of the reward also punishment which has given in the day of judgment. However, reward according to Intellectual Property Right is the gift to appreciate either in the matter of social or economic for the person who makes an innovation or creation. In Islamic perspective, the patent protection is permitted to implement as the kind of the appreciate in the form of reward for the inventor who creates invention as long as the purpose of the getting reward is not for rich his or herself.

In addition, Western is addopted materialistic ideology about the importance of patent protection during 20 years, which arises the monopoly right from the inventor to sell according to his intention to gain the large profit. However, the period of 20 years is not fixed according to Islamic Law. Islam is teaching to help each other for them who need

[146] Khiorul Hidayah*, Perlindungan Hak Paten dalam Kajian Hukum Islam dan Peran Umat Muslim dalam bidang Iptek, Op.Cit* p.89

and unable. So it is possible for the poor state, which needs the access to technology, no need to paid in the high price before the patent protection period expires. In addition, Islam never teaches regarding monopoly, capitalist ideology and materialistic as adopted by almost western countries. Islam is teaching regarding charity with the knowledge, but Allah never forbid the human to get the benefit from service which is already conducted by them as long as not contradict with Islamic teaching.[147]

Furthermore, regarding the perspective of the several scholars related to the patent protection cannot be implemented because it will harm the public need or public interest it can be prevented by the patent flexibility which is regulated under the TRIPs Agreement also implement in national levels such as Indonesia and India. The implementation of patent flexibility is the kind of the exception and limitation to the exclusive right of the patent invention uses without permission of the patent holder because the invention related to the national emergency situation and public interest. So, the patent protection will not be harming the public interest.

2. The Position of Intellectual Property as The Property

In practice, the debate regarding the protection of Intellectual Property is because of the legality of Intellectual Property as the real property or not that will get the right of the propery or not. Property or *al*

[147] Khoirul Hidayah, *Hukum Hak Kekayaan Intelektual, Op. Cit,* p.95

maal according to *al muhith* dictionary means all things that can be owned by someone. According to syara' property is anything that utilizes on something that legally based on syara' such as sell and purchase, lend, consumption and so on.[148] However, several scholars try to give their opinion regarding the meaning of property. In fiqh terminology from discussion Jumhur Ulama regarding property, The meaning of property is not only in the characteristic of the material but also in the characteristic of benefit from the things. Furthermore, Ibn 'Arafah stated; "the property includes an object which can be sensed and abject cannot be sensed (benefit). He defines the property which cannot be sensed as the advantage or benefit which is reasonable impossible refer to him." If the benefit categories as the property such as the implementation of the property, then the benefit also apply property rights as objects of property, as long as the utilization is permitted according to Islam.[149]

Other scholar's opinion, Syafi'iyah and Hanabilah point of view stated that advantage or benefit (*al manfa'ah*) is *amwal mutaqawwamah* (valuable property) because the meaning of advantage is the actually meant by the property. This opinion has strengthened by Imam Syafi'i as stated that become an object of the leasing agreement is the advantage that has an implication until the contract was ended. Even though the owner of the property had been pass away, the contact is still continuing

[148] Aunur Rohim Faqih, Budi Agus Riswandi, and Shabhi Mahmashani, HKI, *Hukum Islam & Fatwa MUI,* First Edition, Graha Ilmu, Yogyakarta, 2010, p.21

[149] Budi Agus Riswandi and Shabhi Mahmashani, *Op. Cit* p. 120

until the contract period is up. In another side, Hunafiyah, as the Islamic scholars, has a different opinion. He stated that the advantage not as the part of property because he defines the property as the thing can be owned and saved. However, the advantage and *haq* is not part of the property but as belonging. [150]

However, almost of scholars is trying to explain the Intellectual Property as *al-maal* because according to QS. Al-Baqarah verse 29 stated that anything that is created in the world has a purpose to utilize by every human. From that surah, many scholars are used the definition of property based on Syafi'iyyah and Hanabilah's opinion. According to Islamic scholars, sometimes the advantage of the object is producing more additional of asset rather than the shape of the object itself. For instance, the number of the price is different between the price to lend the house during a year and the price to sell the house.[151]

Based on the explanation above, it can be concluded that Intellectual Property Right as *al maal* as immaterial in the form of advantage or benefit (*al-manfa'ah*), because the object was protected in the form of creativity or idea, not a thing. Because intellectual property as the property, it means the intellectual property must get the protection and the right.[152] In line with scholar's opinion by Al Gazhali, there is an obligation to protect the property as the one principle is *maqashid al-*

[150] Aunur Rohim Faqih, Budi Agus Riswandi, and Shabhi Mahmashani, *Op.Cit* p.21-22
[151] *Ibid*
[152] *Ibid* p.23

syari'ah as the main purpose of God to determine the regulation. Apart from the purpose is related to realize the benefit of human life. Obviously, Intellectual Property Right is property *(al maal)*, even though Intellectual Property has characteristic of abstract property which is necessary to protected and implemented to realize the Intellectual Property Right. [153]

3. Intellectual Property Right According to Fatwa MUI

In Indonesia, the position of intellectual property right is also explained with the establishment of the fatwa decision of Indonesia Religious Leader (MUI) number 1/MUNAS/VII/MUI/15/2005. The definition of the fatwa is religious advice that given by *mufti* (someone who gives the fatwa) on the basis of the request from someone or group of Muslim. In addition, fatwa according to Ibn Manzhur also stated that the fatwa means the view that is delivered from *faqih* person. [154]

The establishment of fatwa MUI regarding the Protection of Intellectual Property Right began with the anxiety of artists either in the field of fine art or music that most of the creations are copied without the permission of the owner. Therefore, Indonesian Anti-Counterfeiting Society (MIAP) submitted a fatwa request to the MUI for immediately issue a fatwa on the protection of intellectual property rights. Based on

[153] Budi Agus Riswandi and Shabhi Mahmashani, *Loc. Cit*
[154] Aunur Rohim Faqih, Budi Agus Riswandi, and Shabhi Mahmashani, *Op.Cit* p.29

the request from MIAP, then MUI has established the fatwa in the number of 1/MUNAS/VII/MUI/15/2005 the Protection of Intellectual Property Right.[155]

Furthermore, regarding the legal position of Fatwa MUI No.1/MUNAS/VII/MUI/15/2005 in Islamic perspective consist of 3 such as; fatwa establish by *qadli* (court), fatwa establish by request from institution or individual, and fatwa that not establish by *mujtahid* but scholars who are competent in his field. In addition, the legal force of each of fatwa is different each other. For instance, fatwa establishes by the court is legally forced to the decision because it is established by the court which is legally binding. Fatwa establish by the request of the institution or individual is only bind to *mujtahid* and *muqallid* (the one who request the fatwa), but not binding to all of the subject. The last fatwa, fatwa establish by the scholars is not legally binding, but it can be binding for the person who took as the guidance or determine by the state. Thereby, fatwa MUI No.1/MUNAS/VII/MUI/15/2005 is categorized as the fatwa establish by the request of the MIAP that's why the legal position of this fatwa only binding to MUI and MIAP, it is not binding for all of the citizen in general. [156]

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[155] Cindi Muhrani Dewi, *Analisis Fatwa MUI No. 1/MUNAS/VII/MUI/15/2005 Tentang Perlindungan Hak Kekayaan Intelektual Terhadap Mendownload Lagu Secara Ilegal(Studi Kasus Mahasiswa Jurusan Muamalah Fakultas Syariah Dan Hukum Uinsu),* Skripsi, Fakultas Syariah dan Hukum Universitas Islam Negri Sumatera Utara, 2017, p.43

[156] Aunur Rohim Faqih, Budi Agus Riswandi, and Shabhi Mahmashani, *Op.Cit*, p. 48-53

Based on fatwa MUI number 1/MUNAS/VII/MUI/15/2005 defines the intellectual property right as follows:

> *"Intellectual property is wealth arising from the results of thinking of the brain that produces a product or process that is useful to humans and recognized by the state based on applicable legislation, as well as copyright, namely exclusive rights for creators or recipients of rights to announce or reproduce the copyright or give permission for it by not reducing the restrictions according to the applicable laws and regulations "*

In addition, it also stated in the general decision that for the purpose to protect any kinds of intellectual creativity which is get the exclusive right to the patent holder as the kind of appreciation. Furthermore, the purpose for the recognition of the right is to improve the society to create the new creation for the purpose of social interest. In addition, fatwa MUI also defines the legal provision regarding the Intellectual Property Right, it is mentioned that:[157]

1) *According to Islamic law, IPR is seen as one of the "haquq maliyyah" (property rights) that has legal protection ("mashu") as a mal (wealth).*
2) *IPR which is getting the protection from Islamic law as mention in paragraph 1 is the IPR which does not contradict with the Islamic law.*
3) *IPR can become the object of contract ("al-mu'qud'alaih") either the contract of "mu'awadhah" (exchange or commercial), or the contract of "tabarru'at" (non-commercial), also can be reconciled and inherited.*
4) *Any form of violation of IPR, including but not limited to using, disclosing, making, selling, importing, exporting, distributing, submitting, providing, announcing, reproducing, copying, counterfeiting, hijacking other people's IPR without right is injustice and unlawful.*

[157] see the decision of Fatwa MUI number 1/MUNAS VII/MUI/15/2005 regarding the Protection of Intellectual Property Right

Based on fatwa MUI, it can be concluded that Intellectual Property as the immaterial property which is must get the protection for the kind of an appreciation for the inventor who already creates a new invention for the social interest. However, fatwa MUI regarding the Intellectual Property Right did not provide the punishment for violation of Intellectual Property Right. As mention in on fatwa MUI number 1/MUNAS/VII/MUI/15/2005, it only explains that the violation of Intellectual Property Right is injustice and unlawful. This happens because the position of fatwa MUI number 1/MUNAS/VII/MUI/15/2005 is only binding to the MUI and MIAP who as the group of Muslim request for the establishment regarding the position of Intellectual Property Right in Islam. So that, the fatwa MUI not binding to all of the citizen in general.

CHAPTER III

FINDING AND DISCUSSION

A. Introduction

Indonesia and India as the members of WTO have already implemented the regulation regarding patent especially compulsory license in their own legal system. Even Indonesia and India implemented the patent in the same source, actually there are several differences between both of countries especially in the matter of legal systems. Indonesia adopted the legal system based on Civil Law System which means that the decision is based on the regulation. In the other side, India adopted the legal system is based on Common Law System which means that the decision is based on the judge decision. Even though Indonesia and India are having different legal system, overall the patent system is similar to each other. Whereas, Indonesia and India adopted the same patent system of first-to-file which is employed. In which among persons having filed for the same inventions, first one is granted a patent. Therefore, a patent application should be filled properly after conceiving the invention. Therefore, it is advisable to apply for a patent as soon as the inventor's idea of the nature of the invention has taken a definite shape. They do not need to wait until their inventions are fully developed for commercial working before applying for patents. The patent act provides for a mechanism by which the inventor may secure his right to be identified with the invention.[158]

[158] *General Principles Of Patent Law, Loc.Cit*

B. The Comparison Studies Between Indonesia and India on Patent Regulation Regarding Compulsory License

1. Compulsory License Based on Indonesia Patent Law

The implementation of compulsory license in Indonesia Patent Law is started from the obligation of the state member of WTO to implement the Intellectual Property in line with Article 1 of TRIPs Agreement. World Trade Organization (WTO) is the international organization established from the result of negotiation ratified by the state members as the sign of the establishment of WTO. WTO is the trade organization in the world founded based on Marrakesh Agreement. However, Marrakesh Agreement is the result from the negotiation in multilateral trade agreement held by the Uruguay negotiation bellow on GATT (General Agreement on Tariff and Trade). Marrakesh Agreement is effectively implemented by every state since 1995. Thereby, Indonesia has participated in the multilateral trade system since the foundation of GATT. Whereas, Indonesia had been participated as state member of WTO since the foundation of WTO in 1994.[159]

In the beginning, the regulation regarding compulsory license in Indonesia was regulated in Law Number 6 of 1989 until the last amendment in Law Number 13 of 2016 on Patent. In the Law Number 6

[159] Word Press, *Apa Itu World Trade Organizaton (WTO),* posted on June 26, 2013, https://wtoindonesia.wordpress.com accessed on December 19th, 2018 at 9.00 PM

of 1989 regarding Patent, the compulsory license is regulated under Article 81 until 93. The main difference of the Law Number 6 of 1989 is stated that the compulsory license is granted by the District Court. However, the Law Number 6 of 1989 had been replaced by the Law Number 13 of 1997. The amendment is related to the Article 82 which presents an additional provision regarding the request of the compulsory license that can be done anytime after the grant of patent with the reason that the patent holder in the process will be bring the damaging for society. However, the person who grants the compulsory license is still given by District Court. In few years latter, Law Number 14 of 2001 had canged with the Law Number 13 of 1997. In Law Number 14 of 2001, the provision regarding the compulsory license was regulated under Article 74 until 87, but there are several changing of the provisions such as the grant of compulsory license in Law Number 14 of 2001 which is given based on Directorate General of Intellectual Property.

The last amendment, the Law Number 14 of 2001 regarding Patent has been replaced by the Law Number 13 of 2016 regarding Patent. The Law Number 13 of 2016 as the last amendment for the Patent Law is still applicable for patent protection until now and also it is the last regulation that is applied for compulsory license in Indonesia. Moreover, the Law Number 13 of 2016 emphasizes that further provisions regarding compulsory license is regulated with the Government Regulation (previously) and the Ministry Decision (currently). Based on the Law

Number 13 of 2016, the grant of compulsory license is based on the Ministry Regulation. [160] In addition, Law Number 13 of 2016 also provides the compulsory license for the request from the developing country or the developed country which is needed by the pharmaceutical product in Indonesia for the demand of medicine related to endemic, and then pharmaceutical product is possible to be produced in Indonesia and be exported to foreign country. Otherwise, the pharmaceutical product can also be imported from other countries. In the case, if it is not yet produced in Indonesia. To make it clear, the amendment of Indonesia Patent Act is presented in the form of this table 3.1 below;

Table 3.1

The Amendment of Indonesia Patent Act regarding Compulsory License in Patent Protection

Amendment Act	The Changing
Law Number 6 of 1989 on Patent	The provision in Law Number 6 of 1989 stated that the compulsory license is granted by the District Court.
Law Number 13 of 1997 on Patent	The amendment is related to the Article 82. In this article, there is an additional provision regarding the request of the compulsory license that can be done anytime after the grant of patent with the reason the patent or the process of the patent is harm the society. However, the person who is granted the

[160] Niken Sari Dewi and Suteki, "Pelaksanaan Lisensi Wajib Paten Dalam Rangka Alih Teknology Pada Perusahaan Farmasi di Indonesia", *Journal Law Reform,* Volume 13, Number 1, Fakultas Hukum Universitas Dipenegoro, 2017, p.4

	compulsory license given by District Court.
Law Number 14 of 2001 on Patent	There are several changes of the provisions such as the grant of compulsory license in Law Number 14 of 2001 which is given based on Directorate General of Intellectual Property.
Law Number 13 of 2016 on Patent	a. According to the Law Number 13 of 2016, compulsory license is regulated by the Government Regulation (previously) and the Ministry Decision (currently). b. There are additional provisions regarding compulsory license for import and export of pharmaceutical product.

Overall, the amendment of Patent Act in Indonesia aims to improve the Patent regulation. Especially in compulsory license, it is developed by the basic provision regarding the compulsory license. The changing of compulsory license in Law Number 6 of 1989 and the Law Number 13 of 1997 is related to the person who has given the compulsory license by the District Court, and it is changing to the General Directorate of Intellectual Property as mentioned in Law Number 14 of 2001. The changing of provision has improved to make the process of compulsory license simpler than the previous process and to improve the service to society. This procedure is also in line with the procedure implemented by

several countries such as Thailand, Filipina Brazil and China. [161] Further amendments from the Law Number 14 of 2001 to Law Number 13 of 2016 have improvement of the provision in patent act regarding the compulsory license. Law Number 13 of 2016 is better than previous law because the background of amendment in Law Number 13 of 2016 is more extending the provision regarding compulsory license. In addition, the improvement of the government act to protect the social welfare and social safety through the patent utilization is one of backgrounds to amendment the Patent Law. Furthermore, the Law Number 13 of 2016 is more specific to the implementation of patent flexibility through the government use and compulsory license, especially the invention related to the urgent needs and security defense as the one of utilization of flexibility in TRIPs. It can be seen in the Law Number 13 of 2016, there is an addition provision regarding compulsory license for export and import of pharmaceutical products. [162]

In the practice, the provisions regarding compulsory license are not yet be formed, determined, and implemented until now. One of the factors that makes the compulsory license is not yet implemented in Indonesia because Minister Decision regarding compulsory license which is still not yet formed in Indonesia. Mrs Babby Mariati, as the Head of

[161] *Penjelasan atas Undang Undang Republik Indonesia Nomor 14 Tahun 2001 Tentang Paten,* https://ngada.org/uu14-2001pjl.htm accessed on December 28th, 2018, at 2.07 PM

[162] Razilu, *Later Belakang dan Pokok-Pokok Perubahan UU No 12 Tahun 2016 Tentang Paten,* https://lppm.unand.ac.id/images/berita/2016/HAKI/DOC-20161121-WA001.pdf accessed on December 28th, 2018 at 1.48 PM

Legal Consideration Section of the Patent Directorate, stated that the parties of Directorate General of Intellectual Property has already tried to form the minister regulation regarding the compulsory license in patent. In fact, there is an obstacle related to the conflicting interest of certain parties, such as multinational corporation did not desire the Minister Regulation regarding the compulsory license on patent. In addition, Mrs Babby Mariati is said if there is Ministerial Regulation regarding the compulsory license on patent formed, determined, and implemented than the pharmacy companies (multinational corporation) that will decrease at market share in Indonesia.[163] In line with the Dea Melina Nugraheni on her thesis, Dea Melina Nugraheni is stated "the compulsory license is considered as the main problem for the multinational corporation in developed state, especially the requirement for the companies is to introduce their invention and build the facility during 3 years after the date of grant patent, for the purpose to transfer technology." Overall, The existence of this Ministerial Regulation determines the implementation of compulsory patent licenses in Indonesia. Therefore, it is possible for the compulsory license to never be implemented, when the Ministerial Regulation is not yet available.[164]

Generally, compulsory license as the way to limit and except the right of exclusive right is granted by state to use the invention without

[163] Niken Sari Dewi and Suteki, *Op.Cit,* p.4
[164] *Ibid* p. 4-5

oatent holder consent. However, Law Number 13 of 2016 did not give clear explanation regarding definition of compulsory license. It is only mentioned in Article 82. The compulsory license is the license to implement the patent given based on the ministry decision based on request with several reasons as mentioned and explained in the Article 82.

In practice, the implementation of compulsory license in every state is different from each other because TRIPs Agreement and Paris Convention are set as the legal basis to implement Intellectual Property Right. TRIPs Agreement and Paris Convention give the freedom to every state to issue regulation based on their nationality as long as it does not contradict the general provision of the TRIPs Agreement.

Thereby, Indonesia regulated the compulsory license based on Law Number 13 of 2006 on Patent. As mentioned in this article, there are basic criterias to grant compulsory license compulsory license, such as:

a. Compulsory license must have non-exclusive characteristic.
b. Compulsory license is given based on Ministry Decision after the application requested from the parties with the several reasons such as the patent holder who did not implement his duty. In addition, the patent invention is harmful to society and the patent cannot be implement without using the other patent which is stated in Article 82 Law Number 13 of 2016 on Patent.
c. The minister before granting the compulsory license not only consider for the reason as stated in Article 84 but also consider

the several conditions by the minister as stated in Article 84 Indonesia Patent Law.

d. The compulsory license must be granted by the minister for the invention related to the pharmaceutical product for treating the human disease.
e. The use of compulsory license can be used for the purpose of public interest without commercial characteristic and the implementation is based on court decision or competent institution decision.
f. Include the remuneration for patent holder.

Furthermore, the procedure for granting compulsory license is based on the request from the parties to the minister as the one is able to grant compulsory license and has competent to grant the compulsory license through minister decision. During the time period which is regulated under Indonesia Patent Law to request compulsory license in 36 mouths or in three years counting since the date of the grant of the patent protection. After the enough time, then the parties can sue the request for compulsory license with several reasons provided under Article 82 Law Number 13 of 2013 which stated:

> *Compulsory licenses are the license to implement the patent that are given by the ministry decision based on the request with the reason:*
> *a. the patent holder does not conduct the obligation to make a product or using the process in Indonesia in line with article 19 paragraph 1 during 36 (thirty-six) months after granted a patent;*

b. *the patent has already implemented by the patent holder or get the license in the form and with the way that harms the society;*
c. *the patent as the development result that already given previously cannot be implemented by using another patent that still in the protection.*

Whereas, the ministry before granting the compulsory license must considere to give the compulsory license when the several condition as stated in Article 84 was fulfill by the parties. The considerations for the ministry consist the application requested by the applicant or his attorney including the evidence to prove the ability to implement the patent. Furthermore, the applicant or his attorney was attempted to take a step during 12 months for getting the license from patent holder which was based on the reasonable requirement and condition, in fact there is no result. In addition, the decision for the compulsory license as mentioned in Article 88 paragraph 4 stated that the decision must include the non-exclusive characteristic, reason for the grant compulsory license, evidence, time duration, amount of remuneration, requirement for the expiration of compulsory license, scopes of compulsory license, and the other things that required to protect the parties interest fairly.

The last, the ministry must consider the implementation of patent in Indonesia will be properly and give advantage to society. Besides that the consideration of the ministry is needed to consider the purpose for the acceptor of the compulsory license to use the license as stated in Article 100, the purpose must be in the matter of public interest and not for

commercial, or it is implemented based on the decision of the court or other institution.

In addition, there is specific provision regulated the compulsory license special for the invention related to pharmaceutical product. In this case, the invention of pharmaceutical product must grant directly by the minister. It is mentioned in Article 93 Law Number 13 of 2016 regarding Patent, it is stated:

a. *The Minister may provide a compulsory license to produce pharmaceutical products that is already granted by patent protection in Indonesia for the treatment of diseases in humans.*
b. *The Minister may provide a compulsory license for the import of pharmaceutical that is already granted by patent protection but cannot be produced in Indonesia for the treatment of diseases in humans.*
c. *The Minister may provide a compulsory license to export pharmaceutical products patented and produced in Indonesia for the treatment of diseases in humans based on requests from developing countries or undeveloped countries.*

In addition, the implementation of compulsory license is not the one and only used to avoid monopoly right. Indonesia Patent Law also regulates the using of government use of the special invention that can be implemented by the government itself. As mentioned in Article 109, the government can implement the patent in Indonesia based on some consideration such as the state securities and the society interest.

In the practice, Indonesia has not yet implemented the compulsory license because of political interest. However, the implementation of government use in Indonesia began with the

establishment of President Decree on the access of "antiretroviral" medicine. At the time, the medicines of antiretroviral are still protected by patent through President Decree Number 83 of 2004 about the implementation of the patent by government toward the antiretroviral. Furthermore, the government gives the reward to the antiretroviral medicine patent holder in the amount of 0.5% from the selling value of the medicine of antiretroviral. The patent holder of the medicine is Biochem Pharma INC with the time duration of patent implementation in 7 years and 9 years. Moreover, in 2007 the President Decree Number 83 of 2004 has been replaced with the President Decree Number 6 of 2007. In that President Decree, the government appoints a medicine factory to produce the antiretroviral that the patent held by the foreign pharmaceutical company who resolve epidemic of HIV/AIDS. Furthermore, in 2012 the President Decree Number 6 of 2007 was replaced by President Regulation of Republic Indonesia Number 76 of 2012 regarding The Implementation of Patent by The Government Towards Antiviral and Antiretroviral Medicine. [165]

Thereby, Indonesia established the regulation on antiviral and antiretroviral medicine to avoid the negative impact of the patent protection which can lead the invention right to the monopoly, as well as the increase of the high price of the invention. In order to fulfill the certain condition in the society especially in the matter of medicine, the

[165] Khoirul Hidayah, *Hukum Hak Kekayaan Intelektual, Op.Cit* p.87

government must perform several efforts such as the implementation of government use and compulsory license to make the affordable price of the medicine for society. Hereby, the healthiness of the society must be fulfilled, in order to prevent the serious disease such as HIV/AIDS, so that it will not spread wider to other. Since Indonesia is still becoming the consumer of the technology which cannot produce the medicine in the matter of HIV/AIDS drugs, the government use and compulsory license is necessary to be implemented because the disease of HIV/AIDS is kind of infectious diseases which must be noticed by the government to minimize the spread of the disease in a way of providing the affordable price of the medicine to be consumed by the patient of HIV/AIDS. Even though the use of compulsory license still has not yet been implemented in Indonesia, but there is the provision to regulate the compulsory license and also the implementation of government use has already implemented to avoid the negative impact.

2. Compulsory License Based on India Patent Act

The implementation of compulsory license in India Patent act is not really different from Indonesia. Since the state is the member of WTO it means that the states member must implement the intellectual property right in line with the TRIPs Agreement. In the fact, India has been participated in WTO since January 1st, 1995 and listed as a member of

GATT since July 8th, 1948.[166] The participation of India as the state member makes the compulsory for India implement in line with TRIPs Agreement. Especially for the patent protection, India was established the regulation on Patent Act through the India Patent Act which has been amended several times, the last amendment was in 1970 patent act that is replaced in 2005. The several amendments in India Patent Act happened because of several influence on patent protection of pharmaceutical products.

The first regulation on patent protection is Indian Patents and Design Act in 1911. This act brought patent administration under the management of Controller of patent for the first time.[167] The Indian Patent and Design Act in 1911 is also provided for the grant of compulsory licensing for the case related to misuse or abuse of patent right. In addition, any interested person could sue the request of the compulsory license after the expiration of three years counting from the date of granting patent. After the applicant given to the government then the controller who grant of compulsory license must be considered any several conditions to approve the compulsory license such as the invention is held in the territory of India; the request is based on the reasonable terms; the reason for deny the compulsory license is

[166] World Trade Organization, *India and The WTO*, https://www.wto.org/english/thewto_e/countries_e/india_e.htm accessed on December 19th, 2018 at 9.20 PM

[167] Controller General of Patents, Designs & Trademarks, *History of Indian Patent System,* http://www.ipindia.nic.in/history-of-indian-patent-system.htm accessed on December 28th, 2018, at 3.30 PM

reasonable for export the invention that produce in India is not being supplied; and for the reason of condition imposed by the patentee upon the grant of license under the patent the use or sale material is not protected by the patent or establishment or development of commercial or industrial activity in India.[168]

A few years later, the committee felt that the existing provisions in the Indian Patents and Design Act 1911 were inadequate related to the case of patent abuse. In short, Indian Patents and Design Act 1911 had been replaced by Patent Amendment Act 1950, the grounds for compulsory licensing widened. The main addition to the existing grounds was that a compulsory license could be requested if:[169]

i. It is due to the conditions imposed upon the use of a patent or a sale of a patented article, commercial or industrial activities were being hampered.
ii. The Government of India felt that this would be in the interests of consumers or the industrial development of the country. The government could also apply for a compulsory license to be granted to it in order to enable private parties to work the patent.

A few years ago, Patent Amendment Act 1950 has been replaced by Patent Act 1970. The grounds on which a compulsory license can be

[168] Shamnad Basheer, "Compulsory License Regimen in India: Past, Present and Future," *Op.Cit* p.2
[169] *Ibid* p.4

granted under the Act into the following categories such as abuse which is related to patent right (dealt with broadly under Section 84) and the invention which is related to public interest (dealt with broadly under Section 92). However, the Patent Act 1970 does not really cover the invention related to the pharmaceutical product as the one of the society interest. Because of this reason, it is becoming the replacement purpose of the India Patent Act 1970 into India Patent Act 2005. In this act, there are several additional provisions such as compulsory licensing of the mailbox application related to patents and the compulsory licensing of pharmaceutical patent with a view to enabling exports to countries with no manufacturing capabilities. The mailbox application is provided by the applications claiming that the pharmaceutical invention that would be accepted and put away in a mailbox to be examined. The Act provides in the case of those mailbox applications that results in the grant of a patent automatically would issue to those generic companies that made a 'significant investment' and 'producing and marketing'. These medicines are covered by the mailbox application prior to 2005. In addition, Patent Act 2005 is also added the provision related to the pharmaceutical product which is not existed in previous act. This provision focuses on the compulsory license for pharmaceutical patent in term of enabling exports to countries with no manufacturing capability explained in Section 92a India Patent Act 2005. [170] To make it clear, table 3.2

[170] *Ibid* p. 5-6

describes and compares the changing of amendment in India Patent Act.

Table 3.2

The Amendment of India Patent Act regarding Compulsory License in Patent Protection

Amendment Act	The Changing Provision
India Patent and Design Act in 1911	Compulsory license is applied to the controller for grant the compulsory license for any several conditions such as; the invention is held in territory of India, the request is based on the reasonable terms, the reason for deny the compulsory license is reasonable for export the invention that produced in India which is not being supplied, and the reason of condition imposed by the patent holder upon the grant of license under the patent. The use or sale material is not protected by the patent or establishment or development of commercial or industrial activity in India.
Patent Amendment Act in 1950	The reason to apply the compulsory license is more specified if it is related to commercial or industrial activities that were being hampered. Furthermore, the Government of India felt that this would be in the interests of consumers or the industrial development of the country. The government could also apply for a compulsory license to be granted to it in order to enable private parties to work the patent.
India Patent Act 1970	The grounds on which a compulsory license can be granted under the Patent Act are categorized into the following categories such as abuse of patent right (dealt with broadly under Section 84) and public interest (dealt with broadly under Section 92).

India Patent Act 2005	In this act, there are several additional provisions such as compulsory licensing of the mailbox application related to patents and the compulsory licensing of pharmaceutical patent with a view to enabling exports to countries with no manufacturing capabilities.

Overall, the provision regarding compulsory license in India Patent Act 2005 is better than previously, because India Patent Act 2005 provided the provision regarding the compulsory license for the pharmaceutical product. Even the development of technology in India is more advanced than other developing countries, but the public interest is more important than anything. India still has the problem regarding the social health that should be solved by the government. The main problem is the patent protection not fulfill the requirement for the medicine. It will influence to the price of medicine which becomes higher the consequently, there will bring damage to the society and welfare of the society. In the practice, India is the one of the developing countries which has huge number of the poor society without the existence of health insurance. Because there is no existence of the health insurance, it makes the cost of the society health is fulfilled by the government. Therefore, it needs the provision regarding compulsory license for the purpose to ensure the patent for the medicines to not be misused by the patent holder

through the exclusive right.[171]

The implementation of compulsory license in India is different from Indonesia. Indonesia does not implement the compulsory license, but India has implemented the compulsory license. The first compulsory license was granted by the Patent Office on March 9, 2012 to Natco Pharma, an Indian company, for generic production related to drug Sofernib tosylate sold under the brand name Bayer Corporation's Nexavar, a drug used for the treatment of Liver and Kidney cancer. [172] Based on Section 84 Patent Act 1970, the controller found the reasonable requirement of public with respect to the patented invention that had not been satisfied since only 2% of total kidney and liver cancer patents were able to access the Bayer's drug. Furthermore, the controller, as the authorize subject, is granted the compulsory license. After getting this compulsory license, Natco is now free to manufacture and able to sell a generic version of Nexavar in RCC and HCC. Natco will have to pay a 6% royalty on the net sales to Bayer at the end of each quarter. Further, it cannot charge more than Rs 8800 for a monthly dose of 120 tablets of the drug. Natco is also committed to donate free supplies of the medicines to 600 patients each year as a condition of the compulsory license

[171] Shamnad Basheer, "The 'Compulsory License' Regime in India: Past, Present and Future", *Op.Cit,* p.38

[172] Aayush Sharma, *Compulsory Licensing- Every Request For Compulsory License Will Not Be Granted and Special Power of The Government in Exceptional Circumstance,* http://www.mondaq.com/article.asp?article_id=576540&signup=true accessed on December 19th,2018 at 5.26 PM

agreement. [173] Based on the fact, the implementation of compulsory license established by the Patent Controller in India for the local factory against Sorafenib makes the price of the drugs fell 97% from the expected, from US $ 5.500 to US $ 175 for each patient in each month.[174]

The use of compulsory license in India is one of the ways to transfer the patent right to the other. In addition, the transferring patent right in India Patent Act can be done in two ways. The first is through the assignment, and second is through the license of a patent. Patent assignment in general is the act of transferring to another the ownership of one's property, it means the interest and right to the property. Assignment of patent right is defined as transferred by the patent holder at all or part of its right, title and interest in a patent or patent application to any other person. In other side, a patent license is the permission for others to make, use or exercise the invention which is otherwise would not be allowed. The patent license is consisted of two such as voluntary license and compulsory license. The voluntary license happened when the right of patentee at his interest, empowers another person to make, use or exercise the patented invention by written agreement. However, the Indian Patent Office and the Central Government do not have any role in such license. In other side, the compulsory license is involved in

[173] Vipin Mathur, "Patenting of Pharmaceuticals: An Indian Perspective", *International Journal of Drug Development and Research,* 2012.
[174] Niken Sari Dewi and Suteki, *Op.Cit,* p.14

the government to take an action for giving the license to make, use and implement the invention.[175] According to India Patent act, there is no clear definition regarding compulsory license. It only mentions the condition and procedure for compulsory license.

In general, the criteria of compulsory license based on India Patent Act 2005 explains that a compulsory license is granted for:[176]

a. Reasonable requirement of the public with respect to the patent invention which is not satisfied, not available in the public and not worked or existed in the territory of India (Section 84)
b. Export in certain exceptional circumstance (Section 92A)
c. In case of national emergency, extreme urgency of public non-commercial use by notification of the Central Government in the official gazette (Section 93)
d. Countries having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problem (Section 92A paragraph 1)

India Patent Act 2005 regarding the compulsory license procedure for grant of the compulsory license as mentioned in India Patent Act amended in 2005, mentions that an application for the grant of the compulsory license shall be made only before making the

[175] Vipin Mathur, "Patenting of Pharmaceuticals: An Indian Perspective", *Loc. Cit*
[176] Harish Cander, Valbhav Choundhary and Vikas Kumar, *Op.Cit* p.27

application. The applicant has made efforts to obtain a license from the patent holder on reasonable terms and conditions, and such efforts were not successful within a reasonable period (six months). The request for compulsory license is given and decided by the Controller General of Patent and Trademarks (Controller) after the expiration of three years from the date of the grant of patent.[177] In addition, it must be fulfill several conditions as stated in Section 84.1, such as:

> *At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:*
>
> *a. that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or*
> *b. that the patented invention is not available to the public at a reasonably affordable price, or*
> *c. that the patented invention is not worked in the territory of India.*

Moreover, if the certain condition as mentioned in Section 84 India Patent Act has already fulfilled by the parties, the compulsory license that is established by the Controller General of Patents and Trademarks (Controller) who has exclusive right authority to grant the compulsory license must be considered to applied in the compulsory license, it is mentioned in Section 84 (6):

> *In considering the application field under this section, the Controller shall take into account:*
>
> *i. the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;*

[177] Aleksandar Ristanić, *Op.Cit* p.32

ii. *the ability of the applicant to work the invention to the public advantage;*
iii. *the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;*
iv. *as to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:*

After the controller believes to grant the compulsory license, there are several requirements and provisions that must be protected by the controller and fulfilled by the applicant as mentioned in Section 90 India Patent Act. The requirements consisted of several provisions such as pay the royalty or the fee to the patent holder, the invention must be available to the public with the affordable price, the license has the main purpose to supply at the market of India and another requirements which must be protected by the controller.

In addition, there are several conditions for the compulsory license not being applicable in case of the national emergency or in circumstances of the extreme urgency or in case regarding public non-commercial use or on establishment of the ground anti-competitive practices adopted by the patentee, it is mentioned in Section 84:

> *Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anticompetitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.*

In addition, the Section 92.3 also mentioned several conditions that listed several exceptions. If it is related to the circumstance of national emergency; a circumstance of extreme urgency; or a case of public non-commercial use, the Controller as soon as possible shall be applicable for the application for such non-application of Section 87.

In addition, India Patent Act also regulated the compulsory license for export of patented pharmaceutical product which is also regulated under Section 92a India Patent Act. As stated in this article, the compulsory license shall be available for manufacture and export of pharmaceutical product to any countries having insufficient or no manufacturing capacity in pharmaceutical sector. However, this provision is in line with Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health. As stated in this provision compulsory license is available only for the (a) the patented pharmaceutical product (b) manufacture and export to any country having insufficient or no manufacturing capacity in the pharmaceutical sector and (c) product addressing the public health problems in such country.[178]

[178] Vipin Mathur, "Patenting of Pharmaceuticals: An Indian Perspective", *Loc.Cit* PM

3. Similarities and Differences between Indonesia and India Patent Regulation Regarding Compulsory License in Pharmaceutical Product (HIV/AIDS)

Indonesia and India as member of World Trade Organization (WTO) must be implemented the provision on Intellectual Property Right in line with the TRIPs Agreement. The TRIPS Agreement requires state members to comply with certain minimum standards for the protection of intellectual property rights. However, state members may choose to implement laws which give more extensive protection than requirement in the agreement as long as the additional protection does not contravene the provisions of TRIPs Agreement. In addition, the TRIPs Agreement gives members the freedom to determine the appropriate method of implementing the provisions of the agreement within their own legal system and practice. As a result, this agreement takes into account the diversity of members' legal frameworks (for instance between Common Law and Civil Law traditions).[179] As mentioned in Article 1 TRIPs Agreement, it is stated that:

> *"Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and*

[179] World Trade Organization, *Frequently asked questions about TRIPS [trade-related aspects of intellectual property rights] in the WTO,* https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm accessed on December 10th, 2018 at 12.58 PM

practice."

Even though the Article 1 TRIPs Agreement as the basic principle of TRIPs Agreement stated that the member is free to determine a method to implement the provision regarding the Intellectual Property Right within their state legal system and practice, but the provision of every state cannot be contravene with the TRIPs Agreement. Based on the reason above, it makes the implementation regarding the Intellectual Property Right in every state member to have the same legal basis which is TRIPs Agreement.

In the practice, the patent protection in this matter the exclusive right was given by the state to the patent holder which lead to the monopoly right. It means that the patent holder can use his right to forbid other parties without his permission an use an act such as produce, sell, lend, offer, use and serve the invention for selling or lending the result of the production that already grant by the patent. The patent holder can also prevent other person to using his invention.[180] The monopoly right, which occurs in the patent right, arises the certain problem when there is misuse of the exlusive right. In the practice, the exclusive right will be beneficial only for the creator of the Intellectual Property Right, but it will be harmful to the customer of the invention.[181] The arising of monopoly right from the exclusive right makes every state to prevent

[180] Muhamad Djumhana and Djubaedillah, *Op.Cit*, p. 195

[181] Endang Purwaningsih, *Perkembangan Hukum Intellectual Property Right, Op.Cit,* p.128

this right with transferring the patent right through the compulsory license. Compulsory license or other use without the authorization of right holder is one of the efforts from the developing countries as the consumer for the invention in technology that usually provides by the developed countries to prevent the monopoly right so the developing countries can use the invention without approval from the patent holder.

Almost all of the states regulated compulsory license in the same source. Especially Indonesia and India also have same legal basis to implement the Intellectual Property Right specifically in patent law that includes compulsory license. The legal basis for the implementation of compulsory licenses in International level is regulated under Article 31 TRIPs Agreement. Even though state member has already implemented the same legal basis which is based on Article 31 TRIPs Agreement, but it still has several differences regarding the procedures and conditions because the provision was made based on the national interest.

As mentioned in Article 31 TRIPs Agreement, the use of compulsory license must be fulfilled by the several terms and conditions, but there is exception if it is related to the national emergency, extreme urgency, and non-commercial use. However, the third condition regarding the exception to grant compulsory license is

directly without any requirement. It is stated in Article 31 paragraph b TRIPs Agreement as followed:

> *"such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a member in the case if a national emergency or other circumstances of extreme urgency or in cases of public non commercial use in situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable in the case of non commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;"*[182]

Based on the Article 31 TRIPs Agreement, the compulsory license can be implemented directly without need for the certain procedure if it is related to the extreme urgency, case of non-commercial use, or national emergency. In the national level, Article 31 TRIPs Agreement as the legal basis of the state member to addopt the compulsory license. However, TRIPs Agreement did not explain and give parameter that condition categorizes as 3 circumstance that makes different interpretation each of state.

In the practice, compulsory license as the way to transfer technology that the tranfer of tecnology is the important thing to transfer the right of the patent holder to another parties. Not only Indonesia but also India has already regulated the certain condition using to transfer

[182] Trade Related aspects of Intellectual Property Rights (TRIPs) Agreement

the technology for the purpose using the invention without need patent holder consent applied by directly for certain condition which is permitted by national regulation. In Indonesia, the transferring patent right can be conducted not only through the compulsory license but also through the licensing agreement and the implementation of patent by the government. In other side, the transfer of patent right based on India Patent Act transfer of tecnology can be through the assignment, and it is through the license of a patent (including voluntary license and compulsory license). Based on the method used by both of countries, it arises the difference regarding the method for transferring patent right. However, in general, the principle of the transferring patent right which is implemented by the countries is permitted and regulated under the TRIPs Agreement.

In specific, the implementation of compulsory license in Indonesia was regulated under Article 81 until 107 Law Number 13 of 2013 on Patent. The procedure of compulsory license in Indonesia has similarities and also differences from the India Patent Act. The similarities of the procedure between both of countries regulation are the compulsory license given by the state power by the request of the parties. The duration for the submission of the request between both of countries are 3 years (36 month) after the expiration date of the patent. However, there is difference in the procedure granted the compulsory license such as the state power or state official which grants the

compulsory license in Indonesia was given by the Minister Decision. So, the parties interest who request to grant the compulsory license must be established the Minister Decision regarding compulsory license than the parties can apply the application to the Minister. In other side, India Patent Act stated that the one who has authority to grant the patent protection is the Controller General of Patents and Trademarks (Controller). The application gives by the controller without need the regulation or the decision like Indonesia, it can be request directly to the controller if the procedure as stated in India Patent Act already fulfill by the parties interest.

In addition, the approval from the grant of compulsory license must be based on several reasons. Here, Indonesia and India also have different standard of the reason to request the compulsory license. In Indonesia, it is regulated under Article 82 about the reason for request which consists of 3 such as:

1. The patent holder does not implemented the obligation to produce the product or use the process in Indonesia at least during 36 month after the grant of patent.
2. The implementation of patent was harmful to the society interest.
3. The patent as the result of development from patent, which is already granted in previously cannot be implemented without using other patent that is still on the protection.

In other side, in Section 84.1 India Patent Act regulated the reason for the controller for giving the compulsory license with several reason, includes:

i. the reasonable requirement from the public or society related to the patent which is not yet fulfilled or have not yet been satisfied.
ii. the invention that already patented is not available to the public with the affordable price.
iii. the invention that has been already patented is not exist in India territory.

Indonesia and India regulations regarding the reason for the request to grant the compulsory license are quite different. In India, the regulation more considers for the public interest with the requirement from the society. However, Indonesia has more consideration for the reason the implementation of patent by the patent holder in product and process, besides the implementation that harms to the society.

In addition, the state power in both of countries is granted the compulsory license with the consideration that is also different in each state. In Indonesia, as stated in Article 84 Law Number 13 of 2013 the compulsory license was given by the minister in several considerations, such as:

1. The applicant or his attorney has submitted the evidence as the proof of the ability to implement the patent by himself.

2. The applicant or his attorney is already trying to take the step at least in 12 months from the patent holder to get the compulsory license, but there is no result.
3. The ministry has the opinion, the patent can be implemented in Indonesia on the economic scale that is worthy and giving the benefit for the society.

Different form Indonesia, in Section 84.6 India Patent Act decided several considerations for the controller giving the compulsory license, as followed:

1. The time has been passed away after the patent protection and the step which is taken by the patent accepter or the license holder to utilize the invention.
2. The ability of the requests for working in the invention to the public advantage.
3. The capacity of the applicant for taking the risk during when provides the capital and uses the invention.
4. The applicant is already doing an effort to get the license from the patent accepter with the reasonable requirement and provision during the time that considers as reasonable by the controller (six months)

According to the provision overall in Indonesia and India is the same basic consideration to approve the granting of compulsory license by the government body. However, it still has differentiation regarding

consideration of state power to grant the compulsory license. In Indonesia, the effort conducted by the applicant is for 12 months, but India is less than the effort which is at least 6 months. After the unsuccessful effort from the applicant then the controller may consider granting the compulsory license.

The compulsory license is usually using the pharmaceutical product because it is related to the social interest. However, in Indonesia and India, the provision regarding the pharmaceutical product especially for the transferring the right has different procedure to each other. In Indonesia, the invention related to the pharmaceutical product is transferred from the patent holder to the third parties not only through the compulsory license but also the implementation patent of the government. Especially for compulsory license on pharmaceutical product is necessary to grant the compulsory license as regulated in Article 93 Law Number 13 of 2016 on Patent, it is stated:

a. *The Minister may provide a compulsory license to produce pharmaceutical products that are given a patent in Indonesia for the treatment of diseases in humans.*
b. *The Minister may provide a compulsory license for the import of pharmaceutical products that are given patents in Indonesia but cannot be produced in Indonesia for the treatment of diseases in humans.*
c. *The Minister may provide 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 countries or undeveloped countries.*

As mentioned in Article 93, the Minister must grant the compulsory license for the invention related to the pharmaceutical product, so it can be granted directly by the Minister. In addition, the provision of pharmaceutical product also can be conducted by the government itself. It is mentioned in Article 109 Law Number 13 of 2016 regarding Patent Law, the government can implement the patent by themselves of related to defense and security of nation, and also related to urgency need and social interest. This regulation was established based on several considerations such as the patent in Indonesia has an important thing to the defense and security of the state and also needed for society interest, it makes government to implement the patent by themselves. In addition, the scope of the condition that can be conducted by the government-self such as the patent in the matter of firearms, ammunition, military explosives, chemical weapon, biological weapon, nuclear weapon, military equipment, pharmaceutical product for overcome the diseases, chemical product that related to the agriculture and animal is needed to overcome pest and animal disease.[183]

In another side, India was regulated the compulsory license specific in the matter of pharmaceutical product as mentioned in Section 92a. This provision is regarding the export of pharmaceutical product regulated under India Patent Act. It is stated that:

[183] Muhamad Djumhana and Djubaedillah, *Op.Cit*, P.178

Compulsory license for the export of patented pharmaceutical products in certain exceptional circumstances:

1) *Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.*
2) *The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory license solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.*
3) *The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license that can be exported under any other provision of this Act.*

As mentioned in Section 92a, the compulsory license in the matter of pharmaceutical product is necessary granted by the controller without any certain procedure or requirement. In addition, there are other conditions which are necessary granted by the compulsory license. It is stated in Section 92.3 in India Patent Act is related to the national emergency, extreme urgency and non-commercial use. As mentioned in this Section 92.3, it is more focus regarding the society health of the citizen that in the explanation stated the Controller immediately implement the compulsory license, and the procedure as mentioned in general on the Section 84 India Patent Act which is not implemented in the condition as mentioned in Section 92.3 and also if there is condition

which may occur including public health crises, related to immunodeficiency syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics. [184]

In much as, the transfer technology is usually implemented for a pharmaceutical product in the matter of HIV/AIDS medicine because HIV/AIDS medicine is the basic need of the society who suffers from HIV/AIDS disease. In order to fulfill the needs of the society and for the purpose to avoid the spread of HIV/AIDS disease the government must be provided the medicine through compulsory license. Compulsory license as one of the efforts of government to provide the medicine for the patient with the affordable price because compulsory license is the license to use, produce, utilize, and offer the invention without the patent holder consent.

Based on both countries regulation regarding pharmaceutical product, there are several similarities. Not only Indonesia but also India, it is necessary to give the parties for using the invention related to the pharmaceutical product. The pharmaceutical product especially HIV/AIDS must be granted by the government to the parties for the purpose to resolve the public health in the society. In order to fulfill the public health, the government must take an action to provide the medicine in affordable price, and the one way to decrease the price of medicine through the compulsory license. In addition, both countries

[184] India Patent Act,1970 *amended by patent*(Amendment)Act, 2005

have also regulated the provision regarding pharmaceutical product based on one legal basis which is under the Article 31 TRIPs Agreement.

However, the regulation regarding pharmaceutical product in Indonesia and India have differentiation. In Indonesia, the invention regarding the pharmaceutical product can transfer the patent right through the compulsory license or implemented by the government itself. In the practice, Indonesia has not yet implemented the compulsory license, but the implementation of patent by the government is already implemented through the establishment of President Decree and also implemented with the giving of remuneration to the patent holder as the compensation determines by the government. For instance, on October 5th. 2004, it has already established the President Decree Number 83 regarding The Implementation of Patent by The Government toward The Antiretroviral Medicines, in that President Decree, there are several types of the medicine that regulate under this decree each of the types during 7 and 8 years with the remuneration for the patent holder an amount of 0,5% from the net selling value. The action conducted by the government is to implement the government use which is based on Article 31 TRIPs Agreement. TRIPs Agreement is giving permission for the WTO member for using the patent without patent holder consent including the implementation of government by the third parties that permitted by the government. The implementation of patent by the government is a decision which gives permission for the

government to produce certain patent inventions that hold by the inventor for the purpose of the defense and the securities including the urgent situation for society health for the public interest. TRIPs Agreement has also required the formation of the request in the nature of non-exclusive, and include the compensation in the worthy royalty for the patent holder. It also must be conducted by an authority or body who observe the implementation of legal mechanism which must be independent.[185] In a few years ago, President Regulation of Republic Indonesia Number 76 of 2012 regarding The Implementation of Patent by The Government Towards Antiviral and Antiretroviral Medicine.

In another side, in India provision regarding the pharmaceutical product, it only can be transferred to the right through the compulsory license that is given by the Controller General of Patent and Trademarks (controller). The controller in India Patent Act has an exclusive right authority to grant the compulsory license. In addition, in Section 92a Indian Patent Act gives more explaination about the compulsory license for export the pharmaceutical product. However, in Section 92a Indian Patent Act, it is more explained regarding the export because of India as one of states who has big pharmaceutical industries, which make India to have the huge number to export the invention related to the pharmaceutical product. For that reason, it makes Indian Patent Act

[185] Muhamad Djumhana and Djubaedillah, *Op.Cit*, p.178-179

presents specifically explaination about the export of the pharmaceutical product rather than import the pharmaceutical product.

To make it clear, the differences between Indonesia and India regulation regarding compulsory license especially for pharmaceutical product is formed in the table 3.3

Table 3.3

The Comparision Regrading Compulsory License Between Indonesia and India

Criteria of Compulsory License	Indonesia	India
Definition of Compulsory license	It is only mentioned in Article 82, the compulsory license is the license to implement the patent that given based on the Ministry Decision based on request for several reasons.	In India Patent Act, there is no clear definition regarding compulsory, it only mentions the procedure and condition to granting compulsory license.
The one who grants the compulsory license	Minster Decision	The Controller General of Patent and Trademarks (Controller)
The Requirement to ask the Compulsory License	1. The patent holder did not implement the product or process of the invention during 36 months. 2. The patent that implemented by the patent holder or accepter is harmful to society. 3. The patent cannot be implemented without the use of other patents which is still in the protection.	1. The reasonable requirement from the society related to the invention which is not yet fulfilled. 2. The invention is not available in the public with the affordable price. 3. The invention is not existted in India territory.

The acceptance of compulsory license	1. The applicant or his attorney can submit the evidence as the ability to implement the patent by himself. 2. The applicant or his attorney already took an effort maximum 12 month to get the license, but is unsuccessful. 3. The minister opinion that patent can give the benefit to the society.	1. The nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention; 2. The ability of the applicant to work the invention to the public advantage; 3. The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted; 4. As to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit.
The purpose of using the compulsory license	1. Public interest that not for commercial; or 2. Implementing the action based on the court decision or related institution.	1. The invention that granted the patent is work in the territory of India without delayed, and as much as possible to be implemented. 2. The interest for every people to work or

		developed the invention in India under the patent protection.
Compulsory license for pharmaceutical product	Compulsory license for pharmaceutical product necessary granted by the minister, but in practice the compulsory license has not yet be implemented in Indonesia. However, another way to transfer the right especially for pharmaceutical product can also through the government used. In here, the government established President Decree Number 83 is replaced by President Regulation of Republic Indonesia Number 76 of 2012 regarding The Implementation of Patent by The Government Towards Antiviral and Antiretroviral Medicine.	Compulsory license for pharmaceutical product necessary granted by the controller. India has already implemented the compulsory license which is granted by the Patent Office on March 9, 2012, to Natco Pharma, an Indian company, for generic production of Bayer Corporation's Nexavar, a drug used for the treatment of Liver and Kidney cancer.
The provision regarding compulsory license for the pharmaceutical product	The specific regulation regarding the compulsory license for compulsory license is regulated under Article 93. As stated in this article, the minister must give the compulsory license if it is related to the pharmaceutical product. In addition, this article is more focus on the imported product rather than export the invention related to the compulsory license.	In India Patent Act, the compulsory license related to pharmaceutical product is regulated in Section 92a, however, this section more focuses on the compulsory license for the export of patented pharmaceutical product in certain exceptional circumstances.

C. Legal Implication of Patent Regulation Regarding Compulsory License between Indonesia and India on Pharamaceutical Product Especially in The Matter HIV/AIDS Medicine

The basic concept of compulsory license is the procedure for the state of third-party licensing in the production of patented good without the need to take the permission from the patent holder or owner. The party through the license is granted to use the invention under the compulsory license that has already been approval. This is clearly a limitation placed on the right of a patent holder in the interest of the public at large and mostly accompanied by insurance of compensation for the patent holder. In line with the theory which is proposed by the Roscoe Pound in the jurisprudence, it is clearly analyzed that the provision of the compulsory licensing is also introduced to maintain the balance between the stakeholders and the common people. The character of compulsory licensing can be easily framed under the same theory from where the existence can be derived. [186]

In addition, compulsory licensing is often called the "eminent domain of intellectual property". This position has required the state as the giver and protector of intellectual property rights and therefore attributes to the state as an inherent power to interfere with these rights where a public purpose requires to be fulfilled. The requirements of the society at large are weighed against the rights of the patent holder and where there is pressing public

[186] Munnazzar Ahmed, *Legal Implications of Compulsory Licensing in India*, Lambert Academic Publishing, November 2013, p.21-22

requirement, then a compulsory license is issued to meet such requirements. Therefore, most patent legislations recognize some form or other compulsory licensing. In the multilateral framework of the TRIPs Agreement, compulsory licensing is recognized as flexibility available to the state members for attaining purposes such as those relating to public health goals.[187]

As mentioned in previous explaination, several countries have already regulated and implemented compulsory licenses such as Indonesia and India. Both countries are regulated the compulsory license as one of government efforts to except and limit the right of the invention owned by the patent holder. The right that grants in the patent protection is regarding the exclusive right as the kind of right for the patent holder to give or not to give the permission for the using and utilizing the invention. However, this protection system has a negative and positive impact. The positive side of this protection are consisted of several matters such as the development of the trade and inovation, the development of the technology, the encouraging of competitive competition in international level, the turn on the invention, and the support the export needs. Otherwise, the negative impact of the exclusive right in the patent arises in the matter of the monopoly right which makes the high price of invention, the company is not fully exploited the invention to the society because of business interest, and also inhibit the spread of knowledge. [188]

[187] *Ibid* p. 23

[188] Endang Purwaningsih, *Pengembangan Hukum Intellectual Property Right*, *Op.Cit*, p. 139

Whereas, the meaning of monopoly right means not all of the people can use or implement the invention because it needs the patent holder consent.[189] Moreover every state, especially in developing countries such as Indonesia and India, is preventing the negative implication of the exclusive right. Monopoly right is the one of negative impact, and to prevent the monopoly right the states are using compulsory license. The compulsory license is implemented in every developing country because the developing countries are still as the consumer who needs the invention related to the technology which is usually come from the developed countries. In order to use, utilize, produce and any else related to the invention the developing countries need the access to use the invention without the patent holder consent which will decrease the cost of the invention. Therefore, the developing countries grant the compulsory license especially for the pharmaceutical product because it is the one of the efforts of the government to prevent the monopoly right from the exclusive right and also to provide the affordable price for the society through the compulsory license.

However, the regulation regarding compulsory license has several legal implications felt by several parties. There are several aspects of implication such as the legal certainty of the compulsory license in the patent protection related to the clear or unclear position of compulsory license regulation, the implication regarding protection of the parties and the right,

[189] *An India Patent Act; An Overview,* http://shodhganga.inflibnet.ac.in/bitstream/10603/137841/9/09_chapter%202.pdf accessed on December 6th, 2018 at 1.01 PM

the last implication is regarding utilization related to the benefit and fair system toward compulsory license in the patent.

1. **The Implication of Compulsory License regarding Legal Certainty**

In the implementing action of the compulsory license, the TRIPs Agreement as one of legal basis for the state members implementing the intellectual property right have already given permission to except and limit the right of the invention. However, as mentioned in Article 1 TRIPs Agreement, the method of implementing the provision can be free based on each state legal system as long as not contradict with the TRIPs Agreement. TRIPs Agreement give the freedom of the member of state, but there are several terms stated in Article 31 TRIPs Agreement as the legal basis of compulsory licenses such as the emergency situation, non-commercial use and emergency situation as the condition which is necessarly granted the compulsory license which is still unclear regulation that makes the state member interpreted based on their national interest. It is caused the difference in the implementation of compulsory license difference each other. Furthermore, it will be difficult if there is the case regarding the position of a compulsory license that each of state has the different point of view. For instance, the several states which are not implementing the compulsory license such as the U.S which is one of states which does not recognize the compulsory licenses. However, other countries such as Indonesia and India who recognize and regulate

the compulsory license will be difficult to solve the problem arised in the future because of the different national interest.

However, the positive side is that the compulsory license for all of the countries has legal certainty for the society because it is clear up the right of the citizen related to the performance of the government provide the affordable price to the society. In other words, it will make the right of the society to live with healthy is fulfilled by the government. As mentioned in Universal Declaration of Human Right (UDHR) which is established on December 10th, 1948 by United Nation. UDHR has established the basic provision for the protection of the social health for every human, it is stated in Article 25 UDHR regarding the right to get an adequate standard of living for the health and well-being of himself and his family.[190] In addition, the medicine that provides by the government also will prevent the spread of disease. For instance, the HIV/AIDS as one of the diseases which is quickly to spread to other people. In this matter, there is an effort to prevent the people who suffer from HIV/AIDS not spread to other people. In order to prevent the spread of the HIV/AIDS, the government must provide the medicine to the citizen in affordable price. High prices of the drug only compromise with the life-threatening diseases like AIDS which give rise to the realization that increasing access to medicines or drugs must be a part of any solution, whether through compulsory

[190] Niken Sari Dewi and Suteki, *Op.Cit* p.10

licensing resulting from improved public relations or initiative of drug makers (inventor). However, the government has already prevented the HIV/AIDS such as education, the empowerment of women, and distribution of condoms as the best way to decrease the AIDS problem. For the treatment, AIDS therapy regimes were too expensive and complicated to be suitable for developing countries. However, the developing countries cannot just consider to prevent, but also to give treatment for the patient who suffers from HIV/AIDS, and to cover the high price the state implement the compulsory license for the pharmaceutical product for providing an affordable price. In addition, there are also difficulties not only to treat the infected patients but also the people who are infected but don't know that they are infected as it will lead to spreading it more in masses. Here the availability of HIV/AIDS medicines becomes more important. All of these factors have made access to AIDS medicines more pressing and realistic objective.[191]

The affordable price of the HIV/AIDS medicines can be fulfilled by the government through the existing regulation regarding the compulsory license. In line with Naomi A. Bass's opinion, he argues that the compulsory license is a very effective strategy for the developing countries to get access to the cheap medicines. He also

[191] Munnazzar Ahmed, *Loc.Cit*

argues based on the research compulsory license can decrease the medicine price by around 75%.[192]

2. Legal Implication of Compulsory License regarding Protection of the Parties

Furthermore, the legal implication regarding the compulsory license is felt especially for the patent holder who has the right of the invention through the exclusive right. In this context, the compulsory license will be more protecting the public interest (society heath) but not fulfill in the entire right of the patent holder. The existence of a compulsory license makes the invention created by the invention will directly use under the license that already gets approval even tough without the patent holder consent. However, the basic right of the patent holder is regarding the giving of permission or not giving the permission to use the invention. Based on the understanding of compulsory license means the license for using the invention without the patent holder consent. Generally, the license is an agreement which has the characteristic of reciprocal relationship. The reciprocal relationship is the agreement that is given the right and obligation for both of the parties. Therefore, in the compulsory license of the patent is not the agreement consist of reciprocal relationship because the

[192] Naomi A. Bass, *The Implication of the TRIPs Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century,* quoted from Tomi Suryo Utomo, *Loc.Cit*

application or the request of the compulsory license conducted by someone and approved by authorizing subject, then the requester can use process without patent holder consent. In addition, compulsory license is not based on the consent of the parties, so that the principle regarding the freedom of the contract is not applicable in the compulsory license because the compulsory license is only one side that the applicant of the compulsory license can use, utilize, produce, sell, and offer the invention without the patent holder.[193] Even though the compulsory license is implemented without the consent of the patent holder, it is still permitted or allowed based on the TRIPs Agreement and several national regulations such as Indonesia and India. It happens because compulsory license as the exception and limitation of the exclusive right was granted by the patent protection for the parties who want to use the invention through the license approved by the government.

In addition, the patent holder fee is not determined by himself, but it is determined by the government or state power. Even though the compulsory license in Indonesia and India still must provide the remuneration or fee to the patent holder, but the patent holder is still not satisfied to the percentage because of the high risk that makes high cost of his invention. The creation of a new innovative product is spent

[193] Agnes Ivonne de Fretes, *Beberapa Masalah yang Timbul dari Pemberian Lisensi Wajib Menurut Undang Undang Nomor 6 Tahun 1989 Tentang Paten,* http://repository.unair.ac.id/11993/2/FULLTEXT-7.pdf accessed on December 14th, 2018 at 4.40 PM

much of money on investment which throw back to the inventor in the form of incentives for that product.[194] In case of pharmaceuticals, the inventor or the patent holder is paid with the fee which is not balanced with his effort and risk. In other words, the compulsory license also has implication related to the decrease of the incentive because the existence of the incentive will influence the development of the invention. In much as, the innovation is encouraged by the existence of the incentive, without the incentive the development of the invention especially the pharmaceutical industry will be decreased.[195] With the implication arises from the compulsory license, it makes several patent holders in developed countries do not want to deliver the innovation in the matter of technology to the developing countries. When there are no inventions that deliver to the developing countries, the countries which are not able to produce the invention will be difficult to fulfill the society need in the matter of medicine.

3. Legal Implication of Compulsory License regarding Utilization

In addition, the legal implication from the existing regulation regarding compulsory license in Indonesia and India is given the benefit for the society and also the government. The existence of compulsory license is one of methods to transfer technology. The

[194] Munnazzar Ahmed, *Op.Cit,* p.38
[195] *Ibid*

importance of transfer technology will be the parameter for economic development. The transfer of technology has several advantages such as solve the obstacle regarding technology, which is need for economic development. According to Etty Susilowati, the activity for the planning of the technology is more efficient and easy to implement rather than the research and development of the technology, which takes more time and the high cost. That's why it is important to implement the compulsory license as the one ways to achieve the transfer technology.[196]

It cannot be denied, the development of the society in the state is mostly influenced by the state ability to overcome the technology. Through technology, a state will sustain very fast growth.[197] In addition, the relationship between economic development with technology transfer and public health is indeed very close. Everything affects each other, and also the interference from the government is also greatly affects. The government must help every step taken by pharmaceutical companies in achieving technology transfer. If the pharmaceutical companies are able to carry out technology transfer, then the state, especially for developing countries, will not depend on the imported drugs. In addition, public health will also be guaranteed

[196] Niken Sari Dewi and Suteki, *Op.Cit* p.9

[197] Budi Agus Riswand and M. Syamsudin, *Hak Kekayaan Intelektual dan Budaya Hukum,* Quoted from, Niken Sari Dewi and Suteki, *Op.Cit*, p.99

because the price of the drug or medicines is relatively affordable. This relationship will affect economic development in every state. [198]

In national level, Indonesia and India felt the benefit for the compulsory license that will minimize the misuses of the right conduct by the patent holder. Especially for Indonesia, it does not only established the provision of compulsory license under the Law Number 13 of 2016 regarding patent but also there is President Decree Number 83 regarding The Implementation of Patent by The Government toward The Antiretroviral Medicines which is replaced by President Regulation of Republic Indonesia Number 76 of 2012 regarding The Implementation of Patent by The Government Towards Antiviral and Antiretroviral Medicine. This regulation becomes the action to prevent the misuse of the exclusive right grant by the patent. Because of Indonesia still as the customer of the invention the compulsory license is more beneficial to develop the technology rather than makes the new invention which is not necessarily the result will be better than previous technology. [199]

In another side, the implication of compulsory license is also felt by India. Even India has the advanced technology, but the Indian courts have opened the gates for the compulsory license because the need of society to grant the health with the several medicines. However,

[198] Niken Sari Dewi and Suteki, *Op.Cit*, p.12
[199] Kartika Widya Utama, *Manfaat Lisensi Paten Bagi Industri Teknologi dan Informasi Indonesia*, Jilid 41 No.3, Universitas Diponegoro, 2012, p.389-390

it makes the implication for the big pharmacy companies which would be to save the other patented drugs before granted compulsory license seeks by the generic drug companies. It will imply the number of the invention related to pharmaceutical product in India will decrease because the companies will save patented medicines. In addition, other implication has felt by India when the companies moving the Research & Development investment to other nation, which will also effect on the foreign direct investment and transfer technology to India. However, nowadays India still needs the foreign direct investment also technology investment. Another implication for the compulsory license for pharmaceutical product will arise if the compulsory license is granted for a patented medicine where an investment is already done and can't be taken back, causing a halt to the economic gain from such a drug which in future will cause lack of investment in the further R&D for more drugs as company needs to manage its accounts also. Only royalty from such a license would not survive the purpose.[200]

In addition, several scholars are trying to explain the several impacts of the compulsory license that will be coming in the future, such as:[201]

a. The impact related to the invention: this is related to the license in several states, which is refused because the consideration

[200] Munnazzar Ahmed, *Op.Cit,* p.42
[201] Harish Cander, Valbhav Choundhary and Vikas Kumar, *Op.Cit* p.29

regarding the compulsory license will be obstructed the desire of pharmaceutical companies in developing countries enter into the research. In addition, they may become dependent on generic medicines as they can easily get it with a marginal cost of investment as compared to research and development costs. Furthermore, pharmaceutical-based research companies will not be able to obtain the cost of research from the market.

b. The impact related to the competition and cost: compulsory license will lead to the increase of the competition because the increasing numbers of the generic companies are participated to capture high market share. This will help to get the most competitive prices for every patient and also the companies will be able to stand up to the market.

c. The impact related to the patient: the compulsory license will be beneficial to the patient in the matter of financial in the developing counties. In order to access the medicines, the utilizing of the invention with the affordable price will be maintaining the social health.

CHAPTER IV

CONCLUSION

A. Conclusion

1. The compulsory license in Indonesia and India has already regulated under national regulation of each state. In Indonesia, it is regulated under Law Number 13 of 2016 on Patent. In another side, India regulated compulsory license under Indian Patent Act in the last amendment in 1970 which was replaced by India Patent Act in 2005. However, there are differences and similarities between both of regulation. The similarities between Indonesia and India regulation is related to the legal certainty of compulsory license for pharmaceutical product is necessary to be granted by the authorize person directly. In addition, Indonesia and India, as the same WTO members, regulate compulsory license as the same legal source which is under the Article 31 TRIPs Agreement. Even though both of the countries have already regulated the compulsory license under the same legal basis, but there are still difference between Indonesia and India regulation regarding compulsory license, which is related to the authorized person who grants the compulsory license. In Indonesia, authorize person is Ministry through the Ministerial Decision. In another side, India Patent Act stated the one who can give the compulsory license is the Controller General of Patent and Trademarks (Controller). In the practice, the implementation of compulsory license regarding the pharmaceutical product in Indonesia is not yet be implemented. Indonesia just implements the government use to

regulate the pharmaceutical product through the Precedent Decree Number 83 which is replaced by President Regulation of Republic Indonesia Number 76 of 2012 regarding The Implementation of Patent by The Government Towards Antiviral and Antiretroviral Medicine. However, India has already implemented the compulsory license for pharmaceutical product through the establishment of compulsory license on March 9, 2012, to Natco Pharma, an Indian company, for generic production of Bayer Corporation's Nexavar, a drug used for the treatment of Liver and Kidney cancer.

2. The legal implication from the regulation regarding compulsory license for pharmaceutical product especially HIV/AIDS medicines in Indonesia and India consists of several aspects of legal implication. The first legal implication is related to legal certainty of compulsory license regulation. Actually, the implication for legal certainty of regulation in the TRIPs is still unclear because there are several terms of the provision which is not described specificly makes the state members interpreted it based on each national interpretation. However, the existence of compulsory license makes a clear position of the human right as mentioned in UDHR regarding the right of the people to feel healthy. The second legal implication is regarding protection of the parties who involve in the compulsory license. The existence of the compulsory license occurs injustice for the patent holder because the existence of the compulsory license makes other parties can utilize the invention without the patent holder consent. In addition, the

right to get the payment is not fully implemented even though Indonesia and India has the same provision to grant the compulsory license with pay remuneration. However, the amount of the remuneration which was determined by the state power is mostly not enough to over come to the cost and the risk from the process and effort. For that reason, there is a price for the risk and cost that have already been spent by the patent holder. The last legal implication is regarding the utilization toward compulsory license in the patent. The legal implication is regarding the utilization toward compulsory license occurs the benefit for the state regarding the development of the innovation and development of the tecnology. It is more definitely developed when it implements the compulsory license rather than making new invention, because the new invention is not necessarily successful, or better than previous tecnology. Furthermore, compulsory license can avoid the monopoly right given to the patent holder. In addition, the compulsory license provides the affordable price especially for pharmaceutical product. In addition, the kind of the exclusive right is not only for appreciation but also to encourage other people to make a new invention. However, if there is a certain exception to limit the exclusive right such as compulsory license, it makes the people afraid to make a new invention because there is no material advantage to patent holder.

B. Recommendation

1. In order to make it clear, as mentioned in Article 31 TRIPs Agreement, there is a statement regarding the necessity to grant the compulsory license such as national emergency, extreme urgency, and non-commercial use. However, the three conditions as mentioned in Article 31 TRIPs Agreement is not explained in the TRIPs Agreement which makes unclear regulation and different interpretation for each of the state. To make it is clear, it better for making a revision or additional explanation through declaration regarding basic concept of the national emergency, extreme urgency, and non-commercial use. As the basic guideline for the state member to implement the compulsory license in one line.
2. The compulsory license was granted by each of government. Indonesia and India as the one who grants the compulsory license to provide the remuneration for the patent holder, but it is mostly not enough to cover the cost for the invention. So, it will be better for the each of state to determine the percentage for giving the remuneration. Even though in Indonesia there is regulation to give remuneration for patent holder in amount 0,5%, but it does not cover up the cost that has already been spent by the inventor. The amount of remuneration at least consider with the humanitarian and non-commercial reason and also economic value of the inventor. Thereby, it is better for the government to determine the appropriate percentage for the inventor at least to cover the cost that has already been spent by inventor.

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