

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

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### **ABSTRACT**

Paten merupakan salah satu perlindungan yang diberikan oleh pemerintah kepada pemegang paten atas penemuannya. Perlindungan yang diberikan oleh negara adalah hak eksklusif yang berdampak terhadap hak monopoli dari pemegang paten. Hal tersebut membuat beberapa negara seperti Indonesia dan India yang merupakan negara anggota WTO dan juga negara berkembang menggunakan fleksibilitas paten. Salah satu penggunaan fleksibilitas paten adalah lisensi wajib. Lisensi wajib adalah jenis lisensi untuk menggunakan penemuan tanpa persetujuan pemegang paten yang diberikan dengan prosedur tertentu. Namun, ada pengecualian untuk memberikan lisensi wajib secara langsung seperti untuk produk farmasi karena terkait dengan kepentingan umum. Permasalahan dalam penelitian ini difokuskan pada (1) persamaan dan perbedaan antara peraturan Indonesia dan India mengenai lisensi wajib produk farmasi terutama dalam hal obat-obatan HIV / AIDS; dan (2) implikasi hukum dari regulasi mengenai lisensi wajib di Indonesia dan India terutama dalam hal pengobatan HIV / AIDS. Hasil penelitian menunjukkan bahwa ada kesamaan antara Indonesia dan India sebagai anggota WTO mewajibkan untuk menerapkan lisensi wajib berdasarkan Perjanjian TRIPs yang mempengaruhi

prinsip umum yang sama. Namun, masih terdapat perbedaan diantara para anggota terutama Indonesia dan India. Perbedaannya terkait dengan subjek yang memberikan lisensi wajib. Lisensi wajib untuk produk farmasi dalam prakteknya di Indonesia belum diterapkan. Selanjutnya, peraturan tentang lisensi wajib untuk produk farmasi dalam perlindungan paten memberikan implikasi hukum bagi Indonesia dan India. Implikasi hukum terkait dengan kepastian hukum untuk lisensi wajib di Indonesia dan India, perlindungan bagi pihak-pihak yang terlibat dalam lisensi wajib, bentuk pemanfaatan lisensi wajib di Indonesia dan India.

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Keywords: Paten, Fleksibilitas Paten, Lisensi Wajib dan Produk Farmasi

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## **INTRODUCTION**

Patent is one of scopes on Intellectual Property Right. 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 (Geneva; WIPO Publication SCP/13/3, 2009:9). To prevent the negative right, the states is implemented the exception or limitation to the invention, or in another word, it is called as 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 can not 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 regulate under Trade-

Related Aspects of Intellectual Property Rights (TRIPs) Agreement and also Paris Convention.

Furthermore, there are several scopes of the patent flexibility such as parallel import, government use, bolar provision, and compulsory license. This Journal explains more deep lyre garding 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.

Further more, 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 exception and limitation with the existence of Article 31 TRIPs Agreement. It has been mention ed 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 an approval from the inventor. The basic of using compulsory license is not only mention ed in the TRIPs Agreement but also taken into consideration to fulfill the requirement to protect the invention. In Article 31 TRIPs Agreement, 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 still provided the uncertain and unclear provision, because there is no explanation regarding the meaning of the public and non-commercial activity. (Riswandi and Syamsyidin, 204:104) For that reason, it makes the different interpretation among state members related to the meaning of public and non-commercial activity.

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 implemented in India can be easier to analyze rather than other countries, who has the possibility to conduct the research.

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. Furthermore, the existence of exception and imitation 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.

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. 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 back ground 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.

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

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?

## **RESEARCH METHODOLOGY**

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 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 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. The approach method used in this research is statutory research approach and comparative approach. This research is used qualitative analysis methods. The data were collected and elaborated in the form

of description and explanation. Then, it was examined or reviewed based on the expert opinion, legal theories, relevant legal studies, article of the statute and the argument of the research herit self in order to obtain the significant and scientific conclusion.

## **FINDINGS AND DISCUSSION**

### **1. Compulsory License Based on Indonesia Patent Law**

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. Based on the Law Number 13 of 2016, the grant of compulsory license is based on the Ministry Regulation (Dewi and Suteki, 2017:4).

Indonesia regulated the compulsory license based on Law Number 13 of 2006 on Patent. As mentioned in this article, there are several basic criteria as 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 84 Law Number 13 of 2016.

- 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.

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 months 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 2016 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 consider to give the compulsory license when the several conditions 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 “anti retroviral ”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 anti retro viral 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 Bioc hem 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. (Hidayah,2017:87)

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 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 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 tosy late sold under the brand name Bayer Corporation's Nexavar, a drug used for the treatment of Liver and Kidney cancer. (<http://www.mondaq.com>) Based on Section 84 India 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 agreement. (Mathur,2012) Based on the fact, the implementation of compulsory license established by the Patent Controller in India for the local factory against So rafenib makes the price of the drugs fell 97% from the expected, from US \$ 5.500 to US \$ 175 for each patient in each month. (Dewi and Suteki,2017:14)

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 the 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 a this 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 the government to take an action for giving the license to make, use and implement the invention (Mathur, 2012). 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: (Cander, Choundhary and Kumar, 2013:27)

- 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 92A)
- d. Countries having in sufficient 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 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. (Ristanić, 2016:32) 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 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:*

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, 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 per this provision the 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 (Mathur, 2012).

### **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) is related to the legal basis of the compulsory license based on Article 31 TRIPS Agreement. Because both of them are the WTO members which 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, there is still difference among state member.

The differentiation of the compulsory license between Indonesia and India consist of:

- a. The one who grants the compulsory license. In Indonesia is based on Minister Decision, in other side India based on The Controller General of Patent and Trademarks (Controller).
- b. The requirement to ask the compulsory license. In Indonesia consist of: patent holder did not implement the product or process of the invention during 36 months; patent that implemented by the patent holder or acceptor is harmful to society; patent cannot be implemented without the use of other patents which is still in the protection. In other side, India regulated that the requirement are consist: reasonable requirement from society that invention is not yet fulfill; invention not available with affordable price; the invention not existed in India.

- c. The acceptance of compulsory license. In Indonesia the minister must be considered: applicant or his attorney can submit the evidence as the ability to implement the patent by himself; applicant or his attorney already took an effort maximum 12 month to get the license, but is unsuccessful; The minister opinion that patent can give the benefit to the society. In other side, the controller in India considered with: the nature of the invention; The ability of the applicant to work the invention to the public advantage; the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted 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.
- d. The provision regarding compulsory license for pharmaceutical product. Generally, the compulsory license in Indonesia and India is necessary if related to pharmaceutical product. However, In Indonesia, the implementation of compulsory license for pharmaceutical product is not yet be formed. It is only through the government use. 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. In other side, 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.
- e. The provision regarding compulsory license for the pharmaceutical product. In Indonesia, 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.

Even though, the regulation of compulsory license especially in Indonesia and India has difference each other, but basic principal of the compulsory license in Indonesia and Indonesia is same. Both of them are regulated the compulsory license as the kind of effort to transfer the patent right without the patent holder consent. This action conducted for the purpose to prevent the monopoly right. In addition, the procedure of compulsory license is basically based on the request or the application from the third parties during 3 years after the grant patent was expired. In specific, both of states provides the grantor of compulsory license to grant the patent invention related to the pharmaceutical product directly without need the certain procedure and process.

### **1. Legal Implication of Patent Regulation Regarding Compulsory License in Indonesia and India Especially in The Matter HIV/AIDS Medicine**

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 invention and the right, 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 necessary 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.

In another side, 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 10<sup>th</sup>, 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. (Dewi and Suteki, p.10) 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 or derto 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 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 found to 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. (Ahmed, 2013:21-22)

The affordable price of the HIV/AIDS medicines can be fulfilled by the government through the existing regulation regarding the compulsory license. Inline 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 argues based on the research compulsory license can decrease the medicine price by around 75% (Utomo,2007).

## **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 health) 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 application or the request of the compulsory license conducted by someone and approved by authorizing subject.

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

(<http://repository.unair.ac.id>).

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 In addition, the patent holder fee is not determined by him self, 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 much of money on investment

which throw back to the inventor in the form of incentives for that product (Ahmed, 2013:38) 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 (Ahmed, 2013:38). 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 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 Ety 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 (Dewi and Suteki, 2017: 9).

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 (Riswand and M. Syamsudin, 2004:99). 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 because the price of the drug or medicines is relatively affordable. This relationship will affect economic development in every state ( Dewi and Suteki, 2017:12)

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 Anti retro viral 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 (Utama, 2012:389-390)

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, 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 royalty from such a license would not survive the purpose (Ahmed, p.42).

## CONCLUSION

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 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. The compulsory license on patent regulation gives legal implication for the state. There are 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 specifically. It 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 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 technology. 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 technology. 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.

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