

THESIS

**JURIDICAL REVIEW ABOUT COMPULSORY LICENSES OF PATENT IN
AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL
PROPERTY RIGHTS AND PATENT OF ANTIRETROVIRAL DRUGS IN
INDONESIA**

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ABSTRACT

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Pharmaceutical products are part of protection of patent, including antiretroviral drugs. Antiretroviral drugs are to help HIV/AIDS victims. The patent holders of antiretroviral drugs have rights to exploit, produce, sell or give license to another holder to exploit it. Hence, it cause that price of antiretroviral drugs is expensive. And not all community can access the drugs. Hence it is needed government policy to produce the drugs with cheap price or free. Hence, government issues policy, it is called compulsory license or the exploitation of patent by government. Problems identification which are discussed are how arrangements of compulsory licenses of patent on antiretroviral drugs based on international regulations, how arrangement of compulsory licenses of patent on antiretroviral drugs in national regulation which are based on international regulations, and also how is the exploitation of patent on antiretroviral drugs in Indonesia. Methodology this research is juridical-normative research. Based on research it is conclude that compulsory licenses of patent on antiretroviral drugs in Indonesia must be consistent with TRIPS agreement, Law of Patent Number 14 Year 2001, Government Regulation Number 27 Year 2004, Presidential Decree Number 83 Year 2004, and Presidential Decree Number 6 Year 2007.

CHAPTER I

INTRODUCTION

1.1 Background

Intellectual Property Rights (abbreviated IPR) are the rights of which arise from the creation of human minds to produce a product or process of which is beneficial for human's life.¹ At this time IPR becomes important issues and gets attention both national forum and international forum. This matter is proven that be included agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in World Trade Organization agreements. And it indicates that starting of era of IPR in the world. Before formed of TRIPS agreement, there have been several conventions which arranged issues about IPR. However, there are not yet the regulations of IPR in just one convention. And there are several conventions which arrange IPR, such as Paris Convention for the Protection of Intellectual Property 1883 and Berne Convention for the Protection of Literary and Artistic Work 1886.

Based on article 2 TRIPS obligates members to obligation of Paris Convention and Berne Convention.² Standards concerning the availability, scope and use of intellectual property rights are³ :

¹ See Direktorat Jenderal Hak Kekayaan Intelektual Departemen Hukum dan Hak Asasi Manusia Republik Indonesia bekerjasama dengan Japan International Co-Operation Agency, *Buku Panduan Hak Kekayaan Intelektual* , Jakarta 2007, p 3

² See A.Zen Umar Purba, *Hak Kekayaan Intelektual Pasca TRIP's*, P.T Alumni, Jakarta, 2005, p. 22

1. Copyrights and Related Aspects;
2. Trademark;
3. Geographical Indication;
4. Industrial Design;
5. Patents;
6. Layout-Designs (Topographies) of Integrated Circuits;
7. Protection of Undisclosed Information;
8. Control of Anti-Competitive Practices in Contractual Licenses.

One of scope of IPR which is related to technology is patent. Based on TRIPS agreement, patent shall be granted to any inventions whether products or processes in all field of technology, provided that:

1. novelty;
2. involve an inventive step;
3. Capable of industrial application.⁴

Hence, it can be concluded that objects of patent are every technology whether products or processes in industrial applicable which give profit. One of example of object of patent is technology to produce pharmaceutical products. Pharmaceutical industry can not hold out without protection of patent.⁵

³ Part II of TRIPS agreement

⁴ Article 27 of TRIPS agreement

⁵ See Cita Citrawinda Priapantja, *Prospek dan Tantangan HAKI pada Industri Farmasi*, Fakultas Hukum Universitas Indonesia, Depok, p. 1

CHAPTER IV CLOSING REMARK

4.1 Summaries

Based on problems identification, result of research which is mentioned about juridical review of compulsory licenses of patent on antiretroviral drugs based on TRIPS agreement and national regulation, and then writer can conclude that:

1. Basically, the patent holder is free to exploit the protected invention or to authorize another person to exploit it. The purpose of patent is to provide a temporary monopoly to rights holders as a stimulus to inventions and their commercialization. The monopoly right is provided by a patent normally only excludes others from making, using or selling that particular invention. However, when reasons of general interest justify it, national public authorities may allow the exploitation of a patent by a third person without the owner's consent. The exploitation of a patent by a third person without the owner's consent is a part of compulsory licenses. The arrangement of compulsory license there has arranged both in Paris Convention for the Protection of Intellectual Property and TRIPS agreement. In Paris Convention for the Protection of Intellectual Property, compulsory license is arranged in article 5A (4). While under TRIPS agreement, the limited possibilities of use without authorization of the right holder are permitted article 30, compulsory licenses under article 31 are another mechanism in which the patented object can be used without the permission of rightful owner. Based on article 31 of TRIPS agreement, the procedural of compulsory license is arranged and also in Doha Declaration is furthermore

arrangement of compulsory license especially about patent on antiretroviral drugs which are medicines for HIV/AIDS victims. And based on article 31 bis of the amendment of TRIPS agreement extended of arrangement about compulsory license specially about exporting and importing of pharmaceutical products.

2. The legal basis of exploitation of compulsory licenses of patent on antiretroviral drugs based on national regulations is Law of Patent Number 14 Year 2001, Government Regulation Number 27 Year 2004, Presidential Decree Number 83 Year 2004 and Presidential Decree Number 6 Year 2007. Based on this regulation, government may either exploit a patent or appoint third party if there is for an urgent need for the sake of the public interest. Because antiretroviral drugs are pharmaceutical products to conduct HIV/AIDS diseases. Basically, these regulations are consistent with TRIPS agreement; however there is one article is not consistent with TRIPS agreement which arranges about the decision of the Government to self-exploit a Patent.

3. The exploitation of patent on antiretroviral drugs by government in Indonesia based on TRIPS agreement, Law of Patent Number 14 Year 2001, Government Regulation Number 27 Year 2004, Presidential Decree Number 83 Year 2004, and Presidential Decree Number 6 Year 2007. Basically, Presidential Decree Number 83 Year 2004 and Presidential Decree Number 6 Year 2007 are consistent with Law of Patent number 14 year 2001 article 99(2) and Government Regulation number 27 year 2004 article 5. The government shall give a 5% compensation fee of the net selling value of antiretroviral drugs to the patent holder. Minister of health appoints

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