

LEVERAGING TRIPS FLEXIBILITIES: EXPLORING GOVERNMENT USE MECHANISM TO ENHANCE PUBLIC HEALTH RESPONSES TO COVID-19

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ABSTRACT

The corona virus COVID 19 outbreak has an impact on 200 countries world wide both developed and developing countries. Concerns arise that this condition would create difficulties for people in developing countries in accessing drugs at a low cost, considering that most patent holders of pharmaceutical products are producers from developed countries. In 2001 there was WTO Ministerial Declaration on Intellectual Property and Public Health, so called DOHA Declaration that issued TRIPs Flexibilities that means in Intellectual Property (IP) system have built the flexibilities to allow member state to implement IP laws and policies that are most suited into national or regional circumstances.

The corona virus COVID 19 outbreak has an impact on 200 countries world wide both developed and developing countries. If found corona virus vaccine, off course developed countries will put the national interest of their country first. On the other hand for developing countries, like Indonesia, the TRIPs Flexibilities can be used for the sake of their national interest in providing public health.

The objective of the research was to analyze The Potential Use of GU mechanism as TRIPs Flexibilities under the provision of “use without authorization of the right holder “ that stipulated in Article 31 TRIPs to improve public health in combating Corona virus COVID 19 and research method was empirical juridical.

The result of the research is that This provision covers 2 (two) different schema that government use (GU) and compulsory license (CL), however TRIPs does not provides certain definition and clear parameters. As a matter of fact the Ministerial of Law and Human Right No. 30/2018 concerning CL just issued and there has been no legal practice in CL. Whereas The GU had ever been used twice in combating diseases that” extremely urgent” for Indonesia , that HIV/ AID and bird flu but the two with different procedures. The GU have some advantages comparing to CL among others, GU can be used either patented drugs or vaccine or non-patented product. The GU can be implemented anytime without awaiting 36 months commencing the filing date of the drug or vaccine concerned, So that the GU will be the most effective schema to exploit any corona virus vaccine from anywhere in the world without violating Indonesian commitment of the WTO/ TRIPs and WHO agenda.

Keywords: Trips Flexibilities, GU Criteria, Pharmaceutical Product, Public Health.

INTRODUCTION

Global health issues has become an issue of common concern. Governments need to address global health issues, including ensuring the growth of the health industry and producers of pharmaceutical products and vaccines. Nowadays, competition in the health industry is getting tougher. Globalization and technological development are increasingly affecting the growth of the health industry. Unfortunately, even though the global health industry continues to show an increase in production and innovation, not all health products

and services are equally accessed by all communities around the globe (Ministry of Foreign Affairs of the Republic of Indonesia, 2019).

One of the issues related to the inequality of access to medicines and vaccines is the mechanism of patents used as an instrument for intellectual property protection. In the global context, pharmaceutical products have also been included as objects protected by patents as stipulated by The Agreement on Trade-Related Intellectual Property Rights (TRIPs). This has raised a long debate between developed and developing countries. Concerns arise that this condition would create difficulties for people in developing countries in accessing drugs at a low cost, considering that most patent holders of pharmaceutical products are producers from developed countries (Ministry of Foreign Affairs of the Republic of Indonesia, 2019).

Following up on the debate, governments from developing countries urged WTO to pay more attention to these problems. Governments then finally agreed on a resolution that reinforced the ties between TRIPs and public health, called the Doha Declaration on the TRIPs Agreement and Public Health (Ministry of Foreign Affairs of the Republic of Indonesia, 2019).

Currently the world is being hit by Corona virus diseases (COVID-19) outbreak that already become pandemic. There are 200 countries affected by corona virus diseases (COVID-19). In America as the highest affected country there are 83672 cases and in Indonesia there are 32.033 cases. Although Corona Virus vaccine has not been found yet, The World Health Organization (WHO) said that the world is developing 70 Covid-19 virus vaccines. Three of them have been tested on humans. Many Indonesian researchers also proclaim that they have invented Corona virus vaccine without any patent registration (Madura Tribun News, 2020). Responding to “extremely urgent need or emergency” of the corona virus vaccine, the utilization of “GU” as a part TRIPs Flexibilities can be the best solution. Based on the research background the research problem of this research:

1. What the IPR as the ownership regime as stipulated in TRIPs Agreement?
2. What the TRIPs Flexibilities criteria particularly for GU, What the GU legal practice in providing drugs or vaccine for the sake of public interest?

RESEARCH METHOD

Research is scientific activity that tries to solve problem systematically using certain method and techniques. This research on law conducted in 2019 for preparing paper as Resource Person in the South Center Workshop (Jened, 2019). The research is juridical-empiric legal research. In the juridical legal research three approaches are employed statute approach, conceptual approach and comparative approach. The result of normative legal research is prescriptive in nature (Christiani, 2016).

Whereas the empirical legal research was carried out with field study and interviewed and questioned the policy maker ministry of Law and Human Right, Head of Food and Drugs Supervisory Body (BPPOM) and manager in pharmaceutical industry. The empirical research focuses on the application of laws in society that look at factors to assess the importance of the social reality of law to construct a new TRIPs Agreement and its flexibilities.

This research also applied analytical descriptive method which describe the implementation of GU in legal practice based on legal theory and any regulation concerned.

In 1995 most of countries in the world reached multilateral agreement on *Establishing the World Trade Organization (WTO)* with the 15 WTO agendas (Long, 1987). One of the WTO Agenda is *Agreement Trade Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods (TRIPs)*. TRIPs is stated as the most comprehensive negotiations in the IPR field because it regulates law enforcement mechanisms. The

provisions regarding GU under the sub title “the use without authorization of the right holder”.

Pursuant to Paragraph sixth of DOHA Declaration recognize that while the international stand harmonization of patent standard helps facilitate and invention in global economy there also be sufficient leeway to accommodate national differences, notably in terms of differing level economic development.

RESULT

The IPR as the Ownership Regime as Stipulated in Trips Agreement

Intellectual Property Rights widely recognized as private right and a private property. There are 2 (two) philosophical theory related to intellectual property rights as a system of property. The Fruit of Labor theory that was put forward by John Locke and the Personality theory that taught by Georg Fredriech Hegel. John Locke was very influent in the countries which practicing Common Law tradition in his proposal “*Life, Liberty and Property*” stated that (Maniatis, 2002):

Labour is mine and when I appropriate objects from the common I join my labor to them. If you take the objects I have gathered you have also taken my labor, since I have attached my labor to the objects in question. This harms me, and you should not harm me. You therefore have a duty to leave these objects alone. Therefore I have property in the objects.

Whereas Hegel that was very influential in the countries that adhered Civil tradition in his proposal “*Right, Ethic and State*” stated that (Drahos, 1996):

“The property is, among other things, the means by which an individual could objectively express a personal, singular will. In property ‘a person exists’ for the first time as reason... the will which is free in and for itself, as it is in its abstract concept...the person must give himself an external sphere of freedom in order to have beings as idea”.

Both John Locke and Hegel began with the natural law theory which originated from morality” what is good and what is bad” Natural right are derived from natural tangible goods. John Locke refers to right associated with one’s effort whereas Hegel refers to right associated with personality (Roisah & Raharningtyas, 2019). According to Locke one’s effort in creating intellectual creation must be valued as incentive for further creativity. Hegel complete the Locke concept that intellectual creation as manifestation of personality that should be awarded means the awards not merely economic compensation but the recognition of moral rights. With a system of private property rights thereby the owners have right to exclude others from using their intellectual creation.

TRIPs have also engaged with the political constellation between *developed countries* as a technology manufacturers and *developing countries* as a technology user. Argued that the recognition of technology and the special rights of new technology owners as *comperative advantages*, creates competitiveness to support economic growth. Therefore a more stringent and creating rules for international ownership regimes are needed. New ownership law mechanisms that are appropriate for the development of abstract and material characteristics of knowledge, the aim of which is to save the technology they have for a longer period of time and greater regional and political (geopolitical) reach. As a result, it can cause large losses to the developed world, and protect these rights as a substitute for high risk from research and development activities (Kaehler, 1997; Brown, 1994).

Whereas technology users (developing countries or undeveloped countries) need

acceleration to absorb technology to achieve development goals and the need for technology dissemination. Strict ownership regimes will hinder the dissemination of technology and devices because this impedes access to technology and free flow of information. The IPR system as a ownership regime must make a system of development policy and must be flexible enough to be accepted according to the specific characteristics in each country, the level of development and the priority of the socio-economic goals of the country concerned. They believe that access to IPR protection will strengthen the structure of monopolies and oligopolies and increase the cost of acquiring technology and weaken their development opportunities (Kaehler, 1997; Brown, 1994).

According to Prof Josef Drex basically WTO has the main objective "Fair Competition" (Drexl, 2004) which means "*open equitable, just competition which is fair as between competitors and between any of his customers*" (Black, 1996). In order to achieve *Fair Competition* there are 3 (three) legal instruments that must be enforced, namely (Drexl, 2004; Jened, 2006):

1. *Intellectual Property Law.*
2. *Anti-Monopoly Law or Competition Law;*
3. *Unfair Competition Prevention Law;*

IP law aims at promoting the progress of science and useful art by securing limited time to authors, inventor and designer the exclusive right to their respective intellectual creations against piracy and counterfeiting (Holmes, 1983; Jened, 2006; Jened, 2014) *Anti Monopoly Law or Competition Law* aims at ensuring the existence of the market as a place of *fair competition*, and to respond aggressively to anti-competitive conduct (Clarke & Coronas, 2005). Or example, it is prohibited from monopolistic practices, conspiracy, etc. *Un-fair competition prevention law* aims at preventing unfair competition and/or any act of competition contrary to honest practices in industrial or commercial matters, for example, *misleading consumers, false allegation* t in the course of trade ect (WIPO, 1997). These instruments can be seen in the following side triangle which can be rotated depending on the case at hand (Jened, 2010) (Figure 1):

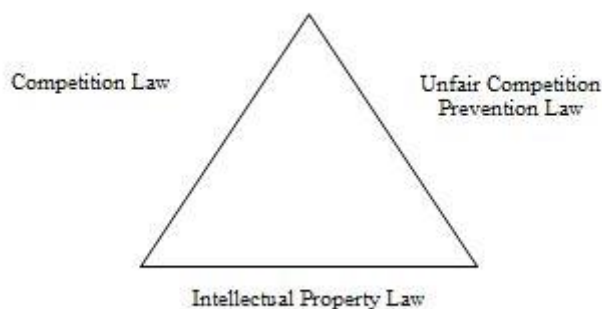


FIGURE 1
INSTRUMENT OF 3 (THREE) LEGAL THAT MUST BE ENFORCED

The TRIPs Agreement has become the influential international agreement ever agreed on intellectual property rights. In addition, the TRIPs Agreement is able to cover 2 (two) world legal traditions, namely Common Law and Civil Law (Merryman, 1967).

There is also the political constellation of the *North* and *South*. The US-led North Country wants an ambitious and comprehensive agreement for IPR protection standards as a whole, for example by emphasizes the period of protection and dispute resolution through *GATT* as a requirement for domestic dispute resolution procedures and procedures for the

authority of customs agencies. most developing countries are concerned that excessive protection of IPR will become a barrier to the validity of trade and strengthen the monopoly power of *multinational corporations* and reduce technology transfer and harm developing countries because of the increase in the cost of acquiring technology. They also asked for guarantees that the company, which was mostly from developed countries, was not permitted to abuse its monopoly rights with harmful means (Kostecki, 1991; Evenson, 1983).

Trips Flexibilities Criteria Particularly for GU and Its Implementation in the Pharmaceutical Products

Pursuant to Article 1 Paragraph 1 of TRIPs Agreement regarding with Nature and Scope of Obligation that:

Member shall give effect to the provisions of this agreement. Member 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. Member shall be free to determine the appropriate method of implementing this provision of this Agreement within their own legal system and practice.

This provisions is a legislative choice (Jened, 2006) for member state to implement the TRIPs agreement that suitable with their national interest and legal politic in order to achieve their National Goals. TRIPs Agreement apply the Paris Convention for Industrial Property Rights as a protection minimum standard (Article 2 TRIPs Agreement). TRIPs also apply national treatment principle (Article 3, the most Favored Nation Principle (Article 4), the objectives (Article 7), the principle (Article 8).

TRIPs Flexibilities that first emerged in Doha Declaration 2001 that means: the Intellectual Property (IP) system have built in flexibilities to allow member state to implement IP laws and policies that are most suited into national and regional circumstances (WIPO, 2020a). Then in 2006 the Commission on Intellectual Property Rights, Innovation and Public Health completed its Report and the member states of World Health Organization (WHO) implemented the main recommendation by establishing an intergovernmental working group to draft a Global Strategy and Plan Action on Public Health, Innovation And Intellectual Property.

Next in 2008 the Global Strategy and Plan Of Action On Public Health Innovation And Intellectual Property was adopted in Resolution WHA61 (WHO, 2020) This global strategy aims among other thing, at improving and delivering access to health products and medical devices by effectively overcoming barrier to access. More recent in 2013, the WHO issued the measurement that include an intensive study on access to medical technologies and innovation, conducted collaboration with the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) as well as release of its Zero Draft Global Plan for the Prevention and Control of Non Communicable Diseases 2013-2020. Various forms of technical assistance have been provided by WIPO to low and lower middle income countries in formulating IP laws and policies using TRIPs Flexibilities (WIPO, 2020b). GU as TRIPs flexibilities stipulated in Article 31 TRIPs as follows:

Other use without Authorization of the Right Holder”:

Where the law of a Member allows for other use⁷ 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 and 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 of a**

national emergency or other circumstances of extreme urgency or in cases of public noncommercial 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 public 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 semi-conductor technology shall only be for public noncommercial use or to remedy a practice determined after 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) any 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 interests 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 other 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 other independent review by a distinct higher authority in that Member; 7 "Other use" refers to use other than that allowed under Article 30. Page 334
- (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 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.

Pursuant to Article 31 bis TRIPs, the concept "of use without authorization of the right holders" covers two different concepts that compulsory license (CL) and government use (GU) which both have physical equality which is carried out by force and without the volunteerism of the right holder/owner, but have some differences. However TRIPs Agreement does not provide those parameters.

According to Bambang Kesowo, for developed countries the absence of definite parameters in the TRIPs Agreement is used by them to vent their reluctance to tolerate the implementation of compulsory license and provide an opportunity for them to build leverage. On the other hand, the absence of this parameter is not common, it is considered as a hidden blessing for developing countries (Kesowo, 2005) (Table 1).

No.	Description	CL	GU
1.	What	Non working patent; Working partially; Patent implementation contravenes with public interest; Cross licensing	National defense National interest; Public interest; Non -commercial purpose

2	Who	Any party; Granted a decision by DGIP	Government only; Government institution appointed by government; Granted by Presidential decree or the Ministerial regulation concerned
3	When	After the expiration of period 36 months	Any time; After the patent granted; After the Permit of Drugs Distribution by FD Supervisory Agency (BPPOM)
4	How	With substantive examination; With remuneration; With annual fee; Can be revoked.	No substantive examination; Non commercial purpose; Limited in manner; For government supply only.
5	Implementation	None	Anytime

Article 31 TRIP is a rule limiting the exclusive rights of Patent holders which is the basis “*GU*” with criteria as follows:

- (a) Shall be considered on its individual merits;
- (b) Shall be considered as national emergency or other circumstances of extreme urgency or in cases of public non-commercial use;
- (c) Shall be without making a patent search,
- (d) Shall be non-exclusive;
- (e) Shall be non-assignable;
- (f) Shall to supply of the domestic market;
- (g) Shall be subject to adequate protection of the legitimate interests of the persons so authorized,
- (h) Shall be an adequate remuneration in taking into account the economic value;
- (i) Shall be subject to judicial review;

So the general parameters applied to “Government Use” is the 12 parameters stated in the provision letter (a) to (l) of Article 31 TRIPs Agreement which can be divided into 4 (four) main issues that are:

- a. Grounds as scope of the object (What);
- b. Subject who entitled of the implementation (Who);
- c. Time period (When), and
- d. Terms and conditions (How)

The exploitation Patent by government stipulated in World Intellectual Property Organization (WIPO) Model Law for Developing Countries on Invention which stated that (Gambiro, 1995):

Where the public interest, in particular national security, nutrition, health, or development of other vital sectors of the national economy, so requires, the Minister concerned may decide that, even without the agreement of the owner of patent, a government agency or a third person designated by the patented invention in the country by performing any of the acts “exploitation”, including importation if necessary, subject to payment therefor”.

Indonesia has ratified Agreement on Establishing the World Trade Organization by Law No. 7/1994. As a legal consequence Indonesia has to comply to all the WTO’s Agendas among others, the Agreement of Trade elated Aspect of Intellectual Property Rights (TRIPs). In terms of Patent Indonesia derived TRIPs provision to the Patent Law No. 14/2001 and *GU* stipulated in Article 99 to Article 103 Patent Law No. 14/2001 (Sati, 2003). Pursuant to Article 99 (Paragraph1) Patent Law that:

- (1) *If the Government is of opinion that a patent in Indonesia is very important for the conduct of defense and security of the state and for an urgent need for the sake of public interest, the government may itself exploit the relevant patent.*

- (2) *The decision to self exploit a patent shall be regulated by Presidential Decree after hearing the consideration from the minister and from the minister or head of agencies responsible in relevant field.*

Article 100 Law No. 142001:

- (1) *The provision of Article 99 shall apply mutatis mutandis to any invention for which patent has been requested but which has not been announced is referred to (that relates to defense and security invention),*
 (2) *Where the government does not or has not yet intended to self exploit. the exploitation of such patent may only be undertaken with an approval from the government;*
 (3) *The patent holder as referred to par (2) shall be released from the obligation to pay annual fees until the relevant patent is exploited.*

Article 101

- (1) *Where the government intends to self exploit a patent that is important to conduct of defense and security of the state and for urgent need for the sake of public interest, the government shall notify the patent holder in writing of this fact by setting forth:*
a. the title number of the relevant patent as well as the name of patent holder;
b. reasoning;
c. the period of exploitation;
d. other matters that are deemed significant.
 (2) *The exploitation patent by the government shall be carried out with the provision of reasonable compensation to the patent holder;*

Article 103:

- (1) *De decision of government to self exploit shall be final;*
 (2) *Where the patent holder does not agree with the amount of compensation stipulated by government, he may file objections as a lawsuit to the commercial court;*
 (3) *The process of examining the law suit as referred to par (2) shall not stop the exploitation of the relevant patent by government.*

Article 103

Provisions regarding the procedure of exploitation of patent by government shall be further regulated by Government Regulation.

Then there are Government Regulation No. 27 /2004 on the Use of Patent by Government.

This subsequent by Presidential Decree on Government No. 83/2004 regarding The Use of Patented of Antiretroviral Drug. In the consideration stated that in efforts to tackle HIV/AIDS epidemic in Indonesia are need to provide access to Antiretroviral drugs Nevirapin and Lamivudin to be implemented by state owned Corporation PT Persero Kimia Farma on behalf of Government as follows:

The patented drugs ID 001338 so called Nevirapin belongs to Boehringer Ingelheim had been exploited by PT Kimia Farma within 7 years after the this decree issued that 2004 to 2021. The patented drugs ID 0002473 so called Lamivudin belongs to Biochem Pharma had been exploited by PT Kimia Farma within 8 years after the this decree issued that 2004 to 2022.

Legal relationship between The Republic Indonesia Government c.q Ministry of Health of Republic Indonesia as Principal and Boehringer Ingelheim (BI) or Biochem Pharma Inc. as Third Party, whereas PT Persero KimiaFarma as Recipient of power and authority on behalf of the Republic Indonesia Government for mandate to produce Nevirapin and Lamuvudin drugs to combat HIV/ AIDS diseases in Indonesia. The decision for the implementation patent by the government is final without any substantive examination (Table 2).

No.	Type of Medicine	Patent Holder	Patent Number	Term of Implementation	Executor
1.	Nevirapin	Boehringer Ingelheim (BI)	ID 0001338	7 years	PT Persero Kimia Farma

2.	Lamivudin	Biochem Pharma Inc.	ID0002473	8 years	PT Persero Kimia Farma
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Then in 2005 to 2009 there was an outbreak of bird flu .Realizing that Tamiflu need as a bird flu virus vaccine the Minister of Health issued a Decree No. 300/MENKES/IV/2009 as a Guidelines for the Prevention of Influenza Pandemic Epicenter that granted Permit to PT Persero Kimia Farma (a state owned corporation) to produce Tamiflu from Boehringer Engelheim. Actually this Minister Decree was very comprehensive and complete provisions but unfortunately have not been fully implemented.

In line with this decree, Minister of Health of the Republic of Indonesia, Siti Fadilah Supari have granted Permit to PT Persero Kimia Farma, a state owned corporation as government designated institution to produce Tamiflu from Boehringer Engelheim. This Tamiflu production is only for government supply in providing public health and is not commercialized at all which as follows:

No.	Type of Medicine	Patent Holder	Permit Distribution of FDA	Term of Implementation	Executor
1.	Tamiflu	Boehringer ingelheim indonesia	DKI 1057506701 issued 8-4-2020		PT Kimia Farma for non-commercial purpose government purpose only
2.	Tamiflu	Boehringer Ingelheim indonesia	DKI 057506701 issued 31-12-2018		PT Kimia Farma for non-commercial purpose government purpose only

Those “GU” schemas in the legal framework of the old Patent Law No. 14/2001 and the old Health Law No.23/1992 which both have been replaced by the Patent Law No. 13/2016 and the Health Law No. 3/2009. In the case of Tamiflu , the exploitation of drugs by the government for the sake of public health was done when the drugs concerned has obtained a distribution permit by the Food and Drug Supervisory Agency (FDA) herein after as Badan Pengawas Obat dan Makanan (BPPOM).

DISCUSSION

The analysis of GU as TRIPs Flexibilities in Indonesian legal practice based on some theories. First theories of ownership by John Locke and Hegel. John Locke stating that every human has hois/her own sel, No one has right over somebody else. Every individual has naturally has right own all potential that attach him/her self and all work she/he makes and law provide him/her economic right to his/her creation. While Hegel stated that the concept of individual welfare as a human being when he/she the owner of a certain wealth. The Hegel’s conception completed the Locke’ conception that personality implied the moral right. Based on these theories the pharmaceutical products inventor has not only economic right but also moral right for their intellectual creation that technology invention. So the

inventor or the pharmaceutical producer deserve to get legal protection as “property or ownership right.

Second, the theory of innovation. Patent is a system to provide protection of inventors exclusive rights and incentive for innovation resulting from research and development (R&D). Patents have the primary function of serving as metering devices for society to measure an invention. The value Social welfare and economic growth depend on technological innovation which not only facilitate a more efficient utilization of available scarce resources but also provide access to new resources (Munzer, 2002). A patent is an exclusive right granted by the state to an inventor for his invention in the field of technology for a certain period of time carrying out the invention himself or giving license or approval to another party to implement. Invention in broad sense involves the development of new product or new process or new improvement of those and new organization for an industry. There are 4 (four) types of innovation (Harhoff, 2004):

- a. Industrial innovations;
- b. Endogeneous or exogeneous innovation;
- c. Innovation in the mechanism of industrial growth;
- d. Innovation through a technology consortium.

Fundamentally it is recognized that technological change very important for market efficiency and patent become a reward or incentive for the new invention in market efficiency.

Third, the theory of the state role by Friedman who stated that there are 4 (four) role of government (Friedman, 1971): Firstly, the state as provider make itself responsible for the provision of social services so as to ensure minimum standard of living for all. Secondly, the state function as regulator uses various leverages of control notably the power to regulate. Thirdly, the state as entrepreneur which operates certain sector sectors of the economy either through semi autonomous government department or through state owned corporations. Fourthly, the state as umpire the state as repository of legislative, administrative and judicial power must evolve some standard of justice as between different sector of economy some of which are state enterprises (Friedman, 1971).

According to the word “state” is abstract for of public legal entity, while the word “government is a concrete form of the state that runs the state or country. The term government means:” The whole class or body of office holders or functionaries in the aggregate upon who devolves the executive, judicial, legislative and administrative business of state (Black, 1996).

If we make an analogy” Government use” with the term “ government purpose” which means :” one which has for its objective the promotion of public health, safety, moral , general welfare, security, prosperity, and contentment of the habitants of a given political division” (Black, 1996). The subject who entitled to ‘GU are:

- a. The government itself ;
- b. The third parties appointed by government.

No	Description	Law No. 14/2001	Law No. 13/2016
1	National security:	<ul style="list-style-type: none"> • Firearms; • Ammo; • Chemical weapons; • Biological weapons; • Nuclear weapons; • Military equipment; 	<ul style="list-style-type: none"> firearms; ammo; military explosive; interception; tapping; reconnaissance encryption devices;

2	Public Interest:	<ul style="list-style-type: none"> . for the sake of public interest: a. Pharmaceutical products that are need to deal with infectious ; diseases that are very broad (epidemic); Chemical product related to agricultural; Veterinary medicine needed to dealt with pests and diseases that are widely spread. 	<p>Emergency and public interest:</p> <p>Pharmaceutical; biotechnology agricultural products at an expensive price; disease that cause death ; diseases that cause significant disability; An emergency public health. ; disease that cause death ; Chemical and biotechnological agricultural products that needed for food security; Animal medicine that needed to combat pests that have wide range of outbreaks; Process or product to cope with disasters natural or environmental</p>
3	Commercial purpose	Expressly stated	Implicitly
4	Extremely emergency	Implicitly	Expressly
5	Implementation	Many	None

Currently the world is being hit by Corona virus diseases (COVID-19) outbreak that already become pandemic. The status of pandemic occurring over wide geographic area and affecting an exceptionally high portion of the area. Indonesia experienced case H5 N1 bird flue in 2005. Vietnamese and Indonesian strain virus had been sent to World Organization Collaborating Center (WHO) CC for risk management to be diagnosed in order to produce a virus seed basic ingredient in making vaccines., but it turned out ironically vaccine maker are developed countries. In preventing the same things happened, Indonesia should optimize the GU provision to exploit any patented corona virus vaccine from any other countries in the world. In addition the GU provision under TRIPs Flexibilities can used as safeguard without violating the commitment of TRIPs Agreement and other WHO agenda.

CONCLUSION

The TRIPs Agreement stipulates minimum standard of patent protection as stipulated in Article 27 -34. However based on Article 1, 2 and 3 connected with Article 7 and 8 there a legislative choice and flexibilities for a member country to regulate patent protection according to the need of its country.

Indonesia has ratified Agreement on Establishing the WTO which include TRIPs Agreement and derived it into the old Patent Law Number 14/2001. In the legal framework the old Patent Law No. 14/2001 and the old Health Law No.23/1992 Indonesia had implemented the “GU” the patent exploitation by government to provide antiretroviral drugs in combating HIV/AID(2001-2004) and to provide tamiflu in case of bird flu H5N1 (2004-2009).

Considering the Corona virus COVID-19 vaccine have not been invented yet the GU schema should be the best solution for the near future to provide the concerned vaccine for the sake of public interest. However inventor Indonesia should be encouraged to apply for patent registration before proclaiming has invented corona virus COVID-19 vaccine to avoid “lack of novelty” of their invention when it comes to be patented.

The most significant advantages to use the “government use” schema that provisions of the exploitation by government that should be (1) Carried out in limited manner; (2) Supplied to domestic need; (3) Provided to noncommercial purpose.

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