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Abstract

The pandemic of Covid-19 and the urgent global needs to immediately obtain an effective drugs or Covid-19 vaccines have impacted the competition of pharmaceutical inventions and the patent registration of drugs or Covid-19 vaccines. However, this circumstance raise pro and cons. There is concern that there will be a conflict between the economic interests of the patent holder and public interest. Patent rights granted to the inventors or pharmaceutical companies has caused difficulties of the State to provide medicines or vaccines to the public since the production and distribution of it has been fully under their control. In this regard, the government use and compulsory license mechanisms are believed to be the most likely policies by the Government for balancing the use of exclusive rights and the economic interests of patent holders. It allow the Government to access and exploit patented inventions without prior consent from the patent holder, but at the same time the patent holder still get the protection and their rights.

Keywords: Patent, Government Use, Compulsory Licence, Covid-19
A. Introduction

December 2019, the corona virus outbreak was first discovered in Wuhan, Hubei province, China. Recorded 14.7 million people infected, and died at least 610,200 people in just a few months.1 The massive spread and high mortality rate, made the World Health Organization (WHO) declared the outbreak as a public health emergency of international concern on January 30th, 2020 and subsequently designated as a pandemic on March 11st, 2020.2 Coronavirus is a group of viruses that can cause disease in animals or humans. Several types of corona viruses are known to cause respiratory tract infections in humans ranging from coughs and colds to more serious ones such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS).3 A new type of coronavirus found to cause the disease COVID-19. In more severe cases, this infection causes pneumonia, acute respiratory syndrome, kidney failure and even death. Supposing that SARS is believed to be transmitted from civets, while MERS from camels, the source of the corona virus itself is still unknown.

Study from the Chinese Journal of Bioinformatics said that the Corona virus was thought to be carried by bats.4 Meanwhile, a study from the Journal of Medical Virology suspected that the virus came from snakes.5 Piers Beirne said bamboo rats, hedgehogs and civets

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were the cause of the coronavirus.\(^6\) Newly, China’s health authorities said the virus originated from a market selling wild animals in Wuhan that was illegally traded. At this time, apart from the unknown origin of the Covid-19 virus, the drug and vaccine for Covid-19 have not yet been found. In fact, according to WHO data, on July 25th, 2021, globally it has been reported that 193,657,752 people have been confirmed positive for Covid, and 4,154,660 people deaths.\(^7\) Meanwhile in Indonesia, according to the Covid-19 Handling Task Force, 3,166,505 people have been confirmed positive.\(^8\)

The Covid-19 outbreak has dramatically impacted many regular aspect of human life. The Indonesian government has taken countless legal, economic, health, and social policies to prevent and reduce the spread of the virus. In conclusion, on June 2020 the government has implemented the policy to make peace with the covid-19 namely “New Normal”. The virus itself is predicted to persist for a long time, even Bill Gates predicts that at least Covid-19 will be over by the end of 2021.\(^9\) It based on the reason that the covid vaccine has been mass-produced, and is fairly distributed throughout world community.

In order to meet the need for a Covid-19 drug and vaccine, the global scientific community with great enthusiasm and willingness has been sharing knowledge as soon as possible about potential treatments and coordinating efforts to clinical trials. However, it is undeniable that there are still some obstacles with the existence of mono-

lies and privatizations carried out by several countries and private companies through their patents. As Joseph E. Stiglitz points out that commercial pharmaceutical companies have for decades privatized and locked away public knowledge by extending control over lifesaving drugs through unwarranted, frivolous, secondary patents and by lobbying against the production of generic drugs.¹⁰ Suppliers will charge high prices, forcing maintenance rationing downstream. If there is no strong public intervention, lives will be lost, especially in developing countries.

The same problem will also apply to Covid-19 drugs and vaccines (when they are discovered). Unlike Jonas Salk’s polio vaccine, which was immediately available and free of charge,¹¹ most vaccines hitting the market today are patented. For example, PCV13, the multi-strain pneumonia vaccine currently given to infants, is known to cost hundreds of dollars because it is a Pfizer monopoly. Even though Gavi, the Vaccine Alliance, subsidizes some of the cost of vaccines in developing countries, many people still cannot afford them. In India alone, although the vaccine generates an estimated $5 billion in revenue for Pfizer each year, there are 100,000 new preventable infant deaths from pneumonia.¹² Julio Nogues argues that patent protection of drugs only gives the pharmaceutical industry a huge advantage.¹³ Patent holders who are mostly pharmaceutical companies will monopolize drug distribution, and this is legitimized by patent rights.

Covid-19 makes it very clear that such monopolies cost human lives. Monopoly control over the technology used in virus testing has hindered the availability of more kits for rapid test.\(^\text{14}\) For example, 3M Company, which holds 441 patents including “respirator” masks or “N95” masks, which has made it difficult for new manufacturers to produce these products. To make matters worse, the granting of patents for the three drugs considered the most effective for treating COVID-19, namely *Remdesivir*, *Favipiravir*, and *Lopinavir/Ritonavir*, prevents competition and threatens the affordability and supply of new drugs.

Since Covid-19 hit the world, at least several countries have registered patents for drug inventions that are claimed to be effective in treating Covid-19. The first recorded patent is held by a vaccine made in China developed by Chen Wei’s team.\(^\text{15}\) Furthermore, Russia also registered a coronavirus vaccine developed by the Gamaleya Research Institute of Epidemiology and Microbiology.\(^\text{16}\) Even *Remdesivir*, a drug that is claimed as most effective at present to treat Covid-19, has been patented by the US biotechnology company, Gilead Sciences. It was first developed specifically to fight Ebola in 2013-2016.\(^\text{17}\) Indonesia as the highest of Covid-19 infected country in Southeast Asia, recorded 377,541 cases and 12,959 people deaths\(^\text{18}\) in May 2020 through the Agricultural Research and Development Agency (Balitbangtan) of the Ministry of Agriculture (Kementan) finally patented 3 Corona antivirus products based on essential plants (Eucalyptus) in the form of Aromatic Antivirus, Antiviral Inhaler Po-

\(^{16}\) *Ibid*
tion, and Nano Encapsulated Antivirus Powder Potion.\textsuperscript{19}

In the most common patent system in the world, registration and granting of patent protection, for example on patents for medicines and medical devices, there are no restrictions on emergency situations, such as the case of the Covid-19 pandemic. This means that if the drug, vaccine or medical device meets the patent criteria, which is novelty, contains an inventive step and industrial applicable, then the product can be patented\textsuperscript{20} and obtain exclusive patent rights, even though the drugs are needed in entire world communities.

However, some people believe that the necessity for the availability of a Covid-19 vaccine makes the exclusive of patent must be ruled out. In the name of public interest, drug must be accessible for anyone who needs it. It means drug is not only available, the most important thing is the price also must be affordable. Contrary, from pharmaceutical companies or institutions interest, patent protection for drugs or vaccines Covid-19 is a must and very important. Due to the process of research, development and testing has huge of money, time, and effort. Two different interests must be considered by policy makers. The policy taken must be a policy that on the one hand does not conflict with the provisions of patent law, and on the other hand it must prioritize the public interest.

As has been performed by some countries that have adopted the TRIPs (Agreement on Trade-Related Aspects of Intellectual Property Rights), using compulsory license or government use is a kind of legal measure that they take to conquer the barrier of patent. Compulsory licenses allowing the Government to gain access and using patent by paying reasonable royalties. Similarly, compulsory license also reduces the risk of intellectual property abuse. As a matter of fact, the compulsory license as a policy tool has proven successfully to increase the antiretroviral drugs access to face AIDS epidemic.\textsuperscript{21}

\textsuperscript{20} Law Republic of Indonesia Number 13 Year 2016 Concerning Patent.
\textsuperscript{21} H. Wong, “The Case For Compulsory Licence During COVID-19,” J. Glob.
During this pandemic, countries that have considered using compulsory license include Chile, Canada, and Israel. Then what about Indonesia, has Indonesia’s Patent Law allowed the government to use the mechanism of compulsory license or government use to ensure the availability and access of drugs or Covid-19 vaccines for Indonesian people?

B. Research Method

Doctrinal legal research (pure legal research) is the methodology which this study used. It uses documents of legislation and library materials as the main of study. This research was conducted by identifying the implementation of ‘compulsory licenses and government use’ principles as the flexibility TRIPs in order to protect the interests of national public health, particularly with regard to access drugs and Covid-19 vaccines. The method of thinking used is the deductive thinking method which is the way of thinking in drawing conclusions drawn from something general in nature and the conclusion is intended for something specific. As a pure legal research, it uses the statute approach as the problem solving method, by analysing international and national regulations related to compulsory license and government use mechanism of patent.

C. Drugs Patent and TRIP’s Flexibility

Before specifically discussing the regulation of drug patents, firstly it is important for us to understand the concept of patents adopted in the Indonesian legal system.

Article 1 point 1 of Law Number 13 of 2016 Concerning Patents, states that “Patent means an exclusive right granted to the inventors by the State as the result of his/her invention in the field of...
technology for a definite period of time to exclusively implement his/her given invention or to give consent to other party”.

It means that the inventor has the right to be able to implement/utilize his invention personally or give authorization to other parties for utilize his rights through a license agreement. Indonesia itself adopts ‘first to file principle’ for patent registration. It means that patent rights will only be granted for legal subjects who apply first the invention and who have completed the minimum requirements. There is no protection of rights without registration. Registration is mandatory. The Patent Law was created to protect and respect the inventor’s intellectual property by granting exclusive rights to his inventions in the field of technology for 20 years for ordinary patents, and 10 years for simple patents.\(^\text{25}\) It can be granted only for new technology inventions (called novelty), it has inventive steps and industrial applicable. Including drug patent application.

In Law of Republic of Indonesia Number 13 of 2016 concerning Patents, there are several articles that specifically regulate patent provisions for medicinal products, such as Article 9 letter (b) which stipulates that methods of examination, treatment, treatment and/or surgery applied to humans and/or animals cannot be granted patents. The registration of patents for medicines is carried out through the Directorate General of Intellectual Property (DJKI). Patents for drugs have the same provisions likewise other patents inventions. Patent right is a reward for inventors. It grant to the inventors as the compliment for their hard work. Similarly inventions in the medical field. It needs hard and continuously efforts, research, countless cost. Patent as a legal way to protect and ensure the inventors for get it back. Through patent they got exclusive right to monopolize the utilization, production, distribution, and exploiting it economically. It grants for 20 years before it becomes public domain.

Overthought, patent has many advantages, in the same time it has negativity. Due to the owner of patent right has the monopoly right, accessed for the invention will be limited. It will make the

\(^{25}\) Law of Republic of Indonesia Number 13 of 2016 Concerning on Patent.
product will be expensive for public, especially for medical patent. The granting of patents to the pharmaceutical industry in developed countries tends to have an impact on the selling price of certain medicinal products soaring high for developing and poor countries. This fact makes it difficult for developing countries and poor countries to access and obtain these medicines, while a low R&D culture makes these countries unable to produce and provide their own domestic health needs.

In the international level, the threat of patents for public access becoming real since the World Trade Organization (WTO) includes Intellectual Property Rights (IPR) as one of the agreements that must be followed by participating countries. It is an international agreement under the WTO administration that sets minimum standards for various IPR regulations, including patents, in each of its member countries. The criticism that has been raised for TRIPs is that the agreement adheres to the principle of “one size fits all,” meaning that TRIPs are forced to apply to all countries regardless of the economic status and development in that country. However, if we examined closely, TRIPs actually has the flexibility provisions for patent rights. It give several privileges the countries especially for developing country (DC) and least-developed country (LDC) in implementing the TRIPs standard, including patents related to access to public health. At least the TRIPs agreement has 12 Articles that regulate drug patent protection, and 3 Articles on policies to overcome the effects of drug patents which are often referred to as the TRIPs Safe-guards Article. It can be used as a strategy to overcome the threat of patents on access to public health include Bolar Provision, Parallel Import, Compulsory License, and Government Use.

The Bolar provision provides an exception for interested parties who research patented drugs within a period of time before the

27 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).
patent expires (twenty years). It means that some time before the drug patent expires, generic drug manufacturers are given the opportunity to research the patented drug, the results of which will be marketed after the patent expires.

Parallel import is overseas sales activity for products containing IPR, including Patents, beyond the control of the IPR holder or owner. What needs to be emphasized is that the product containing IPR is not a counterfeit or pirated product. It means that original patented drugs produced abroad can enter a country without going through official channels. Usually the price of the product is much cheaper than the price of the official product.

Compulsory license is a government regulation that allows the state to ‘force’ patent holders on drugs to grant a patent license to the State for a certain period of time accompanied by appropriate compensation to the patent holder. Meanwhile, Government use is the exclusion of patent rights on drugs for the benefit of the state.

D. Regulations of Government Use and Compulsory Licenses on Patent of Drugs or Covid-19 Vaccine

Theoretically, the existence of the TRIPs Safeguards articles in TRIPs Agreement promote developing (DC) and under developed (LDC) countries to take national policies related to the public health of their citizens, including Indonesia. Efforts to gain access to affordable medicines were further strengthened when the Doha Declaration on the TRIPs Agreement and Public Health at the Ministerial Conference was adopted in Doha on 2001. The Doha Declaration on the TRIPs Agreement and Public Health was adopted in response to complaints developing countries for the ineffectiveness of the protective articles in the TRIPs Agreement. The provisions in the Doha Declaration were established to confirm the existence of (the TRIPs Safeguards) as a tool to overcome patent barriers.

The term of Compulsory License is basically unknown in the TRIPs Agreement, but the core principle is contained in Article 31 which states use of a patent without the permission of the patent
holder. In particular, the Article is further emphasized through the clauses of Doha Declaration clauses related to TRIPS Agreement and Public Health by allowing the Government to produce domestically or adopt generic versions of pharmaceutical products requiring permission from the patent holder with the approval of the patent holder through a mechanism known as compulsory licensing.

Paragraph 5 the Doha Declaration state that “(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted, (c) each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency”.

It emphasizes the State right to interpret articles that protect the public health interests as regulated in the TRIPs agreement, including compulsory licenses and national emergencies. Therefore, there is no doubt that the Covid-19 pandemic which is a world health crisis is also a “national emergency” as the reason for the Indonesian government to be able to carry out compulsory licenses as a way to overcome the barriers of drug and Covid-19 vaccines patented, as affirmed in Paragraph 5 [c] of the Doha declaration. This is in line with the statement of Naomi A. Bass who argues that compulsory licensing is a very effective strategy for developing countries to gain access to cheaper and affordable medicines. She also revealed that based on a study compulsory licensing can reduce drug prices by around 75%.

Compulsory license is defined as the government action that allows others to manufacture products or processes that have been patented.


patented without the prior consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO’s agreement on intellectual property—the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.\(^\text{30}\)

Based on the Doha Declaration, it can conclude that there has some requirement need to fulfilled by the country in order for applying the flexibilities, are:

a. “The existence of public health problems that are endemic such as HIV/AIDS, malaria, tuberculosis or other epidemics, thus requiring medicines that are expensive because they are protected by patents;

b. There is a national emergency and the need is urgent. In this regard, each country is given the freedom to define the definition of “national emergency” or “need very urgent” in accordance with the national needs of each country;

c. There are problems regarding the inability and lack of capacity of the State to produce pharmaceutical patents”\(^\text{31}\)

In Indonesia, patent right is regulated in Law Number 13 of 2016 concerning Patents (Paten Law), including mechanism of compulsory licenses and government use. It can be found on Article 18 to Article 107 of Patent Law. Article 93 states that: “(1) The Minister may grant a compulsory License to make pharmaceutical products patented in Indonesia to serve a purpose of medication of human diseases. (2) The Minister may grant a compulsory License to import supply of pharmaceutical products patented in Indonesia yet has not been feasible to be made in Indonesia to serve a purpose of medication of human diseases. (3) The Minister may grant a compulsory License to export pharmaceutical products patented and made in In-


donesia to serve a purpose of medication of human diseases upon request from developing or least developed countries”.

Despite the fact that compulsory licenses allow other parties (licensee) utilize the product or process without the permission of the patent owner or holder, the Law also requires the licensee to provide compensation to the patent holder, Article 92 confirms that: “(1) Compulsory Licensee must provide Remuneration to the Patent Holder. (2) Provisions regarding the amount of Remuneration and method of payment as referred to in section (1) are regulated by a Ministerial Regulation”.

In line with the provisions of the Doha Declaration, the Patent Law also states that the Government may apply a patent without permission from the patent holder in an urgent situation under certain conditions. Among other things, to produce pharmaceutical and/or biotechnology products which are expensive and/or necessary to treat diseases that can cause sudden death in large numbers, cause significant disability, and constitute a Public Health Emergency of World Concern (KKMMD).

In addition to this, it also regulated on Regulation of the Minister of Law and Human Rights Number 30 of 2019 concerning The Procedures for Granting of Compulsory Patent License as amended by Regulation of the Minister of Law and Human Rights Number 14 of 2021 concerning The Amended of Regulation of the Minister of Law and Human Rights Number 30 of 2019 concerning The Procedures for Granting of Compulsory Patent License on Article 33 and Article 34.

With the enactment of this regulation, a compulsory license may be granted to a third party if: “(1) A patent holder does not implement an obligation to manufacture products or use processes in Indonesia within 36 months from when a patent was granted. (2) A patent has been implemented by a patent holder or its licensee in a form and manner that harm the public interest. (3) A patent that resulted from the development of a previous granted patent cannot be implemented without using the other party’s patent that is still valid and under protection”.

Therefore, in the event of a great demand for an essential drug in the community, an application for a compulsory license can be made to the Minister of Law and Human Rights (Kemenkumham) and will be granted with a specified validity period. Compulsory licenses possible applied by individuals, companies, and government agencies. In the event that the application for a compulsory license is granted, the decision shall contain the provisions in Article 26 Paragraph (2) of Regulation of the Minister of Law and Human Rights Number 30 of 2019 which includes the amount of compensation that must be paid by the recipient of the compulsory license. Thus, it won’t necessarily harm the economic right of patent holder.

In addition to the compulsory license, Article 31 of the TRIPs Agreement allows the government to overcome patent barriers for the provision of drugs and/or vaccines for Covid-19 by using the mechanism of government use. In Indonesia, it regulated in Articles 109 to Article 120 of Patent Law, clarified by Presidential Decree of Republic Indonesia Number 77 of 2020 concerning Procedures for the Implementation of Patents by The Government.

There has three kinds of reason to implement the mechanism, are:

(i) Due to national defence and security; or
(ii) Due to urgent public needs; and
(iii) Patent which disturbs or, is violating State defence and security.

Implementation of the patent on the grounds of (i) or (ii) above can be exercised by the Government itself or by appointing another party if the Government cannot exercise by itself. While the patent (iii) above must only be exercised by the Government and without possibility of appointing another party; if the Government cannot or not yet intend to exercise such patent, in that case, the patent may only be exercised by the patent holder but with the approval from the Government.

Patent (i) above includes among others weapon, ammunition, military explosive, tapping, and surveillance. Patent (ii) above includes among others expensive pharmaceutical products, chemical and/or biotechnology products for agriculture, animal medicine for
pest control and/or animal disease. Patent (iii) above includes among other electromagnetic weapon and explosive.

If a third party is appointed by the Government to implement the patent (i) or (ii) above, such third party must fulfil the following criteria: (a) it has adequate facilities and capacity to implement the patent; (b) it will not assign/transfer the patent to other parties; and (c) it possess a good producing/manufacturing methods, distribution and monitoring/supervision practices in accordance with the regulations.

In accordance of Article 13 states that “The implementation of patents that can be done alone by the Government relating to the urgent needs for the benefit of the community, including: (a) pharmaceutical and/or biotechnological products that are expensive and/or necessary to cope with diseases that can result in sudden death in large quantities, cause significant disability, and it is a public health emergency that is troubling the world; (b) chemical and/or biotechnological products related to agriculture necessary for food security; (c) veterinary remedies necessary to combat widespread animal pests and/or diseases; and/or (d) processes and/or products to cope with natural disasters and/or environmental disasters”.

Taking into account the provisions of Patent Law and Presidential Regulation above, it can be seen that the application of patents by the government can be carried out in two fields, are defence and security fields, as well as in the pharmaceutical sector.

In its own history, Indonesia has been implementing Patents by the Government since 2004. At that time the Indonesian Government experienced a shortage of HIV/AIDS drugs, so that Decree of the President Republic of Indonesia Number 76 of 2012 was issued for the Procurement of Antiviral and Antiretroviral (ARV) drugs for HIV/AIDS and Hepatitis B. The Government’s considerations behind the implementation of this patent can be seen from the consideration given to letter (a) of the Presidential Regulation which states: “that in line with the urgent need in the effort to control Human

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32 Presidential Decree of Republic Indonesia Number 77 of 2020 concerning Procedures for the Implementation of Patents by The Government.
Immunodeficiency Virus-Acquired Immuno Deficiency Syndrome (HIV / AIDS) and Hepatitis B in Indonesia, it is necessary to continue and expand the access policies to provide access to Antiviral and Antiretroviral medicines that are still protected by patent”.

In accordance to it, Article 1 of Presidential Decree states that “The Exploitation of Antiviral and Antiretroviral medicines by the Government is intended to meet availability and urgent needs of community for Antiviral and Antiretroviral for treatment of Human Immunodeficiency Virus-Acquired Immuno Deficiency Syndrome (HIV / AIDS) and Hepatitis B”.

In the context of implementing the patent, the Government appoints the pharmaceutical industry as the executor of the patent for and on behalf of the Government, in the implementation of this patent the relevant pharmaceutical industry is required to pay royalties to the patent holder of 0.5% of the net selling value of antiviral and antiretroviral drugs.

Based on the previous explanation, even though the compulsory license and the Government Use mechanism both are allow the Government to use other people’s patents without prior consent from the patent holder, in principle there are differences between it, especially from reasons and procedures for filing. In general, the reasons for applying the compulsory license is based on economic reasons, while the reasons for filing a patent by the government are due to the national interest and the public needs. Furthermore, based on the application, the compulsory license starts with a third party application and the approval for its grant by the Directorate General of Intellectual Property Rights, while the procedure for using patents by the government is carried out through a Presidential Decree after hearing considerations from the Minister of Health. The licensee possible individuals, companies, or government agencies. Contrary, Government Use mechanism implemented by the Government. In order the government is unable to implement a patent by itself, it may appoint a third party to implement the patent – in other words, it can assign what is commonly called a compulsory license.

As a conclusion, Rahmi Jened, Professor at the Faculty of Law
Airlangga University, said it is important to remember that Article 31 of the TRIPs Agreement regulates two different things, namely, government use and compulsory license with two different parameters. First is by using a substantive examination and its implementation is for the government, not for commercial purposes and it has been implemented in Indonesia for HIV and AIDS vaccines. As a matter of fact, there is government use for drugs that do not have a patent such as Tamiflu to treat H5N1 flu. Contrary, for the Compulsory License there is no implementing regulation in Indonesia and the regulation is still controversial also the third party must be waiting for 36 months for one patent to be available in Indonesia. Indonesia has no experience with compulsory license.\textsuperscript{33}

F. Conclusion

The mandatory requirement for applying the compulsory license and government use is the existence of a public health emergency. With the stipulation of Covid-19 as a pandemic by WHO and as a National Disaster through the Presidential Decree, it is sufficient reason for the government to apply the mechanism without prior consent of the patent holder. The huge and urgent needs for drugs and Covid-19 vaccines should be accompanied by strategic policies that can over-ride, for a certain time, the exclusivity of patent rights. Considering Indonesia as a developing country, it is still difficult and constrained to implement, acquire and develop technology in the medical field. Applying the government use or compulsory license mechanism is an obligation. With this mechanism, the supply of medicines can be fulfilled and more affordable. In addition to the clarity of patent regulations, under current conditions, what the Indonesian government and foreign government all the governments of other countries have to do is strengthening international cooperation, especially access to

drugs and Covid-19 vaccine, thus it can immediately mass-produced for all countries.

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The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

The Government Use and Compulsory License


