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COVID-19 VACCINE LEGAL PROTECTION THROUGH PATENT FOR PUBLIC INTEREST

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ABSTRACT

Patents are rights granted by the state to inventors for their inventions in the field of technology for a certain period of time. However, a rigid patent protection can disrupt the public interest. The research conducted by juridical normative legal research methods, statutory approaches, and conceptual approaches. TRIPs Agreement, Paris Convention, and Indonesian Patent Law 2016 are the main objects of study. This research aims to answer the legal protection of the Covid-19 vaccine for the public interest, and disputes settlement mechanism against the Covid-19 patent rights holder in Indonesia. It can be concluded that patents can be implemented by the government without the authority from the patent holder in an emergency situation. In the return, a worth compensation must be given to the patent holder. If a dispute arises, it can be resolved through litigation or alternative dispute resolution (ADR), but preferably through ADR at Intellectual Property Rights Arbitration and Mediation Board (Badan Arbitrase dan Mediasi Hak Kekayaan Intelektual or BAM HKI). The purposes are to empower BAM HKI, as well as to support and promote the enforcement of intellectual property rights in Indonesia.

Keywords: indonesia patent law of 2016; intellectual property rights; international law; paris convention; trips agreement.

I. INTRODUCTION

On March 2020, Coronavirus Disease 2019 (Covid-19) was declared as a pandemic by the World Health Organization (WHO).[1] This was due to a significant increase in patients with Covid-19 and the spread of this virus to various parts of the world.[2] As is known, as of Wednesday (27/1/2021) morning, the total number of confirmed Covid-19 cases in the world is 100,801,465 (100 million), 72,810,592 (72 million) patients have recovered, and 2,164,749 people have died. The impact of this virus has made the affected countries experience a health crisis, including developed countries. This is due to the high rate of spread of the virus in the midst of limited number of facility services. Covid-19 has also affected the economies of various countries due to the paralysis of economic activities caused by various policies implemented to stop the spread of the virus. In the United States, where as of May 2020, more than 26 million people lost their jobs and up to 35 million people lost access to health care due to their job losses.[3]

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[1] BBC, "Coronavirus confirmed as pandemic by World Health Organization" https://www.bbc.com/news/world-51839944, accessed on 1 October 2020.

[2] Kompas.com, "Update Corona di Dunia 27 Januari: 100 Juta Kasus, Update Corona di Dunia 27 Januari: 100 Juta Kasus", https://www.kompas.com/tren/read/2021/01/27/093100765/update-corona-di-dunia-27-januari--100-juta-kasus-who-rilis-pedoman-klinis?page=all, accessed on 27 January 2021; "WHO Rilis Pedoman Klinis Terbaru untuk Rawat Pasien Covid-19", https://www.kompas.com/ tren/read/2021/01/27/093100765/update-corona-di-dunia-27-januari-100juta-kasus-who-rilis-pedoman-klinis?page=all, accessed on 27 January 2021.

[3] NBC News, "U.S. Jobless Claims Reach 26 Million Since Coronavirus Hit, Wiping Out All Gains Since 2008 Recession", https://www.nbcnews.com/business/business-news/u-s-jobless-claims-reach-26-million-coronavirus-hit-wiping-n1190296, accessed on 1 October 2020.

Various parties, both from health institutions and educational institutions (Universities) are trying to develop a Covid-19 vaccine to break the chain of spreading this virus. In September 2020 there were 151 Covid-19 vaccine candidates who were in the pre-clinical trial stage and 41 Covid-19 vaccine candidates who had entered the clinical stage.[4] However, the effectiveness of the use of a Covid-19 vaccine for the entire population in various countries cannot be ascertained. The reason is the Covid-19 virus continues to mutate and in every region has a different type of Covid-19 virus from other regions.[5] The impact of mutations by this virus makes a difference in the type of virus with the type in other countries, namely because of the activity of the virus that adapts to a person's immunity and environmental conditions in a country. Until April 2020, Covid-19 had 3 types, including type A, type B, and type C.[6] Given that this virus is still relatively new, deeper studies and research are needed both about this virus and about the effectiveness of the vaccine that is currently being developed.

According to Anthony S. Fauci, who is a disease expert in the Covid-19 task force in the United States, a Covid-19 vaccine can be found within 12-18 months.[7] However, since the beginning of the vaccine development, there have been questions that have sparked this research, namely how to protect patents if a vaccine from this virus is found. This problem will especially be a problem for countries that adhere to a democratic system, because in general countries that follow this system have a focus on protecting and respecting patents.[8] Based on Article 1 number 1 of Law No. 13 of 2016 concerning Patents (Patent Law 2016), 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 to carry out the invention himself or to give approval to other parties to implement it. Then the right to obtain a patent is the inventor or the person who further receives the related inventor's rights (Article 10 paragraph 1 of the 2016 Patent Law). The person in question is an individual or a legal entity.[9] The problem point of this research is can this Covid-19 vaccine be commercialized because of the urgent need in various countries in the world that need it. Because especially like developing countries should be ready to meet their own public health needs and Patents should not hinder this effort.[10] The exclusive rights of patents are also often used as tools for exploitation for the holder. This has happened in India, where the price of drugs rose 52% due to patents which then contributed to the loss of public welfare by US$ 33 million.[11] Patents once hindered the distribution of drugs to South Africa, which was hampered when dealing with AIDS.[12] In addition, the issuance of mandatory licenses in developing countries is often filed for

[4] World Health Organization, "Draft Landscape of Covid-19 Candidate Vaccines 30 September 2020", https://www.who.int/publications/m/item/draft-landscape-ofcovid-19-candidate-vaccines, accessed on 1 October 2020.
[5] University of Cambridge, "Covid-19: genetic network analysis provides 'snapshot' of pandemic origins", https://www.cam.ac.uk/research/news/covid-19-genetic-network-analysis-provides-snapshot-of-pandemic-origins, accessed on 1 October 2020.
[6] The New York Times, "How Long Will a Vaccine Really Take?" https://www.nytimes.com/interactive/2020/04/30/opinion/coronavirus-covid-vaccine.html, accessed on 1 October 2020.
[7] *Ibid*.
[8] Josh Lerner, "150 Years of Patent Protection", *The American Economy Review,* Vol. 92, No. 2, 2002, p. 221.
[9] Risa Amrikasari, "Bolehkah CV Mengajukan Permohonan Paten?", https://www.hukumonline.com/klinik/a/bolehkah-cv-mengajukan-permohonan-paten-lt53578c1bde025#:~:text=Namun%20perlu%20diingat%2C%20dalam%20Pasal,orang%20perseorangan%20atau%20badan%20hukum, accessed on 4 March 2021.
[10] Frederick M. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO", *Journal of International Economic Law*, Vol. 5, No. 2, 2002, p. 474.
[11] Jayashree Watal, "Introducing Product Patents in the Indian Pharmaceutical Sector – Implications for Prices and Welfare", *World Competition Law and Economics Review*, Vol. 20, Iss. 2, 1996, p. 19-20.
[11] *Ibid*, p. 19-20.
[12] Tomi Suryo Utomo, "Pharmaceutical Patent Protection Versus National Drug Policy in South Africa: A Tension Between International Standards and Domestic Developmental Policy", *Mimbar Hukum*, Vol. 19, No. 3, 2007, p. 420.

cancellation by patent holders who generally come from developed countries.[13] In Indonesia, the majority of hospitals have been dominated by patented drugs rather than generic drugs, the reason being that patented drugs are more economically profitable.[14] On the other hand, there is concern for inventors who will later find vaccines from Covid-19 but their rights deprived and unprotected. Whereas the actual principle of patent protection is, among others, to provide motivation for inventions, encourage investment in development and commercialization, as a reward to individuals who make inventions, and allow exploration for wider prospects.[15] But of course there is a famous adage that is one of the discussions in this study, namely the adage that was mentioned by Cicero, "*Salus Populi Suprema Lex Esto*" which means that the highest law is the safety.

Therefore, researchers will examine the protection of patents in Indonesia which are protected by the constitution and contained in Law No. 13 of 2016 concerning Patents (Patent Law). Researchers will also examine Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement and Paris

Convention for the Protection of Industrial Property ("Paris Convention"). Researchers will examine these two provisions because the Patent Law is a source of law related to patents in Indonesia. Meanwhile, TRIPS and the Paris Convention are sources of law related to patents in a global scope. Then the researchers will also review the latest regulations related to the Covid-19 vaccine, which are contained in Presidential Decree (Perpres) No. 99 of 2020 concerning Vaccine Procurement and Vaccination Implementation in the Context of Combating the Covid-19 Pandemic as amended by Presidential Decree (Perpres) No. 14 of 2021 which amended by Presidential Decree (Perpres) No. 50 of 2021 concerning The Second Amendment of Presidential Decree (Perpres) No 99 of 2020. Based on the descriptions that have been mentioned, the researcher seeks to solve the problems in this study regarding the protection of patents for the public interest. In addition, the researcher will also examine the dispute resolution in the event of an exclusive claim for the COVID-19 vaccine between the exclusive patent holder and the state. By conducting this research, it is hoped that it can contribute to the protection of patents at the global and in Indonesia.

II. RESEARCH METHODS

In the social sciences, the term methodology applies to how one conducts research.[16] The methodology essentially provides guidelines, on the ways in which a researcher studies, analyzes, and understands the environment he or she encounters.[17] The research itself is aimed at understanding events that arise over time. This makes sense, because research aims to reveal the truth in a systematic, methodological, and consistent manner.[18] This research uses normative methods or legal research libraries, namely legal research conducted by examining library materials or secondary data.[19]

This legal research has several approaches, namely:[20]

I. The statute approach

[13] Achmad Amri Ichsan, "Analisis Yuridis Terhadap Lisensi Wajib Dan Pelaksanaan Paten Oleh Pemerintah Berdasarkan Perjanjian TRIP's", *Jurnal Ilmu Hukum Legal Opinion*, Vol. 2 No. 1, 2014, p. 9.
[14] Tomi Suryo Utomo, *Op Cit*., p. 431
[15] Roberto Mazzoleni and Richard R. Nelson, "The benefits and costs of strong patent protection: a contribution to the current debate", *Research Policy*, Vol. 27, No. 3, 1998, p. 274-9
[16] Soerjono Soekanto, *Pengantar Penelitian Hukum*, Jakarta: UI-Press, 2015, p. 6.
[17] *Ibid.*
[18] Soerjono Soekanto and Sri Mamudji, *Penelitian Hukum Normatif: Suatu Tinjauan Singkat*, Jakarta: Rajawali Pers, 1983, p. 1.
[19] *Ibid.*, pp. 13-4
[20] Peter Mahmud Marzuki, Penelitian Hukum: Edisi Revisi, Jakarta: Kencana, 2005, p. 133-6.

The legal approach is carried out by reviewing all laws and regulations related to the legal issues being handled. For research for practical activities, the legal approach will open up opportunities for researchers to study whether there is consistency and conformity between one law and other laws or between laws and the Constitution or between regulations and laws. The results of the study are an argument for solving the issues at hand.

II. Conceptual approach

The conceptual approach departs from the views and doctrines that develop in the science of law. By studying the views and doctrines in legal science, researchers will find ideas that give birth to legal understandings, legal concepts, and legal principles that are relevant to the issues at hand.

II. DISCUSSION AND RESULT

1. Patent Regulation

1.1. Covid-19 Vaccine

Covid-19 is a respiratory disease,[21] which is highly contagious and spreads through direct respiratory air between humans, and through vomit.[22] While vaccines are substances that are deliberately made to stimulate the formation of immunity from certain diseases, so that they can prevent contracting from certain diseases.[23] Although the immune system in the body is one of the factors whether the vaccine will succeed in forming immunity or not.[24] According to Anthony S. Fauci, who is a disease expert in the Covid-19 task force in the United States, the Covid-19 vaccine can be found within 12-18 months. Giovanni Van Empel has an opinion regarding the Covid-19 Vaccine and Virus related to this research:[25]

1. Viruses always mutate but never leave their original shell, for that vaccines can include variations. Until now there has been no solid concern regarding the effectiveness of the Covid-19 vaccine to deal with the development of mutations from Covid-19.
2. The Covid-19 vaccine is given based on the priority of the most vulnerable people, namely the elderly (over the age of 60 years), everyone who has comorbid diseases, and people who are susceptible to being exposed to Covid-19 disease (medical personnel and so on)
3. Regarding the procurement of the Covid-19 vaccine, transparency is needed from upstream to downstream because problems related to vaccines are not only during their development but also their distribution that must be considered. The government as a policy maker must make a clear scheme related to procurement and distribution by fulfilling the principles of transparency and accountability.
4. Indonesia can learn from China regarding vaccine logistics, communication policies to Australia and Singapore, policies regarding technology to Taiwan. Because every country has shortcomings related to dealing with the Covid-19 outbreak, therefore Indonesia cannot just imitate one country but must look at the best practices of each country.

[21] Simran Preet Kaur & Vandana Gupta, "SARS-CoV-2 Vaccine: Reconnoitering the Prospects", *Vaccine Research and Development*, Vol. 1, No. 1, 2020, p.1
[22] Simran Kaur & Vandana Gupta, "Covid-19 Vaccine: A comprehensive status report", *Virus Research*, Vol. 288, 2020, p.1.
[23] Satgas Penanganan Covid-19, 2021, "Apa Itu Vaksin?" https://covid19.go.id/artikel/2021/06/18/apa-itu-vaksin-2, accessed on 23 January 2021.
[24] Alan D. T. Barrett and Dirk E, Teuwen, "Yellow fever vaccine - how does it work and why do rare cases of serious adverse events take place?" *Current Opinion in Immunology*, Vol. 21, Iss. 3, 2009, p. 309.
[25] Giovanni van Empel, interview via online with author, 30 November 2020.

1.2. Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement)

The TRIPS Agreement is part of the World Trade Organization Agreement (WTO Agreement) which took effect on January 1, 1995. The TRIPS Agreement is one of the important documents produced in the Uruguay Final Round in the context of establishing the World Trade Organization (WTO).[26] The WTO itself can be described as a central international economic institution.[27] The TRIPS Agreement is a comprehensive legal umbrella for all intellectual property areas previously protected by international treaties separately.[28] The WTO member countries themselves cannot choose which provisions to follow and which ones not, because if they have agreed, it means that each country must comply with the agreed provisions.[29] This indicates that each country cannot choose which provisions to comply with and which ones not. The TRIPS Agreement itself is fully binding on countries that have agreed to the TRIPS agreement, but of course at the time of the TRIPS agreement it is agreed to give each member a transition period to harmonize it is provisions with local state law.[30]

TRIPs are not designed without a purpose. There is a basic initiating goal which is to reduce distortions and things that hinder the progress of international trade. Then TRIPS has a goal to protect personal rights (to protect private property rights). The member countries themselves agreed to Trips to empower Intellectual Property Rights (IPR) holders by giving roles to the government in their respective countries to assist the rule of law through drafting laws and regulations, as well as creating legal institutions. As a subject of intellectual property law enforcement, the Government cannot take over trips without a proper mechanism, in order to protect the rights of license holders. TRIPs require to compensate rights holders if the government is willing to take rights from license holders taking into account the economic value of the license.[31]

The TRIPS Agreement regulates several things, the first is to regulate general provisions, basic principles, regarding the obligations of each member country to implement the provisions of the TRIPS agreement and apply them in their respective national laws. This is intended to provide protection, law enforcement against technological inventions and facilitate technology transfer and distribution by taking into account the rights of inventors and their use in supporting economic and social welfare, as well as a balance of rights and obligations. Then what is regulated in the TRIPS agreement, among others, is the standard provisions for regulating types of IPR, covering the subject and object of IPR, substantive requirements and formal procedures. The third TRIPS Agreement regulates the obligations for member countries to implement the TRIPS Agreement law enforcement. The regulated obligations include, among others, providing efficient and inexpensive procedures in order to avoid losses that are greater than the ownership of IPR itself. The fourth thing that is regulated in IPR is the terms and conditions in obtaining and maintaining IPR including the allowed procedures. Then the fifth thing that is regulated is regarding preventive efforts against IPR disputes and the settlement mechanism.[32] The fifth regulates the effectiveness of the TRIPS Agreement. For developed countries this agreement is

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[26] Affrilyanna Purba, et al, *TRIPs-WTO & Hukum HKI Indonesia Kajian Perlindungan Hak Cipta Seni Batik Tradisional Indonesia*, Jakarta: Rineka Cipta, 2005, p. 1.

[27] John H. Jackson, "Dispute Settlement and the WTO – Emerging Problems", *Journal of International Economic Law*, Vol 1, No.3, 1998, p. 329

[28] FX Adji Samekto, "Dampak Berlakunya TRIPS Agreement Terhadap Pelaksanaan Konvensi Keanekaragaman Hayati", *Hukum dan Pembangunan*, Vol. 34, No. 1, 2004, p. 37

[29] James Cameron and Kevin R. Gray, "Principles of International Law in the WTO Dispute Settlement Body", *International and Comparative Law Quarterly*, Vol. 50, No.2, 2001, p. 248.

[30] *Ibid*.

[31] Tony Hanoraga and Niken Prasetyawati, "Lisensi Wajib Paten Sebagai Salah Satu Wujud Pembatasan Hak Eksklusif Paten", *Jurnal Sosial Humaniora*, Vol. 8, No. 2, 2015, p. 171.

valid for one year since the signing of the WTO convention. In contrast to developing countries, which are given 4 years and underdeveloped countries, which are given 10 years. Developed countries are also given the obligation to provide facilities for the transfer of technology, technical and financial cooperation to developing and underdeveloped countries. Finally, the authority of TRIPs is to oversee the implementation of agreed agreements, assist in dispute resolution and carry out collaborative activities between international and WIPO bodies. In the closing provisions, it is regulated regarding the review and amendment of the TRIPS Agreement. This can be done by member countries with exceptions on security grounds.[33]

1.3. Patent Rights Arrangement in Indonesia

In Indonesia, regulations regarding intellectual property have existed since 1844. These regulations include the Trademark Law, Patent Law, and Copyright. The application of the rules in the Netherlands East-Indies (the name of Indonesia in the colonial period) was due to the fact that at that time it had been a member of the Paris Convention for the Protection of Industrial Property since 1888 and a member of the Berne Convention for the Protection of Literary and Aristic Works since 1914. Patent Law for the first time in Indonesia it took effect on July 1, 1912 through *Octrooiwet* 1910 S No.33 yis S 11-136, S 22-54.[34] During the Japanese occupation period, 1942 s.d. 1945, all laws and regulations in the field of intellectual property rights remain in effect. At the time of Indonesia's independence, all laws that did not conflict with the 1945 Constitution remained in effect. The Patent Law became a regulation that was sacrificed because it was considered contrary to the 1945 Constitution.[35] The reason the patent provision was revoked was because it contradicted the Sovereignty of the Republic of Indonesia, precisely because the patent registration mechanism had to be submitted to the Netherlands.[36]

Reported in the website of the Director General of IP,[37] In 1953 the Minister of Justice of the Republic of Indonesia issued a related national regulation on patents through the Announcement of the Minister of Justice No. J.S. 5/41/4, and the Announcement of the Minister of Justice No. J.G. 1/2/17 which regulates the temporary filing of foreign patent applications. On 10 May 1979 Indonesia ratified the Paris Convention for the Protection of Industrial Property (Stockholm Revision 1967) based on Presidential Decree no. 24 of 1979. Indonesia's participation in the Paris Convention at that time was not yet full because Indonesia made an exception (reservation) to a number of provisions, namely Articles 1 to Articles. 12, and Article 28 paragraph (1).[38]

In 1988 based on Presidential Decree No. 32 it was stipulated that the Directorate General of Copyright, Patents and Marks (DJ HCPM) be established to take over the functions and duties of the Directorate of Patents and Copyrights, which is one of the echelon II units within the Directorate General of Law and Legislation, Ministry of Justice. Then on October 13, 1989, the House of Representatives approved the Bill on Patents which was later ratified by the President on November 1, 1989. The law was numbered as Law no. 6 of 1989 (Patent Law 1989). The purpose of the ratification of the 1989 Patent Law is to provide legal protection and realize a legal protection for the technology

[33] Tri Setiady, "Harmonisasi Prinsip-Prinsip TRIPS Agreement Dalam Hak Kekayaan Intelektual Dengan Kepentingan Nasional", *Fiat Justisia: Jurnal Ilmu Hukum*," Vol. 8, No. 4, 2014, pp. 602-3.

[34] Handaya Surya Wibawa, "Masalah Paten Ditinjau Dari Segi Hukum", *Hukum dan Pembangunan*, Vol. 15, 1985, p. 84.

[35] Direktur Jenderal Kekayaan Intelektual, "Sejarah Perkembangan Perlindungan Kekayaan Intelektual (KI)", https://www.dgip.go.id/tentang-djki/sejarah-djki, accessed on 7 November 2020.

[36] Handaya Surya Wibawa, *Op.Cit.*, p. 84.

[37] Dirjen Jenderal Kekayaan Intelektual, *Op.Cit.*

[38] *Ibid.*

industry, especially related to inventions. The ratification of the 1989 Patent Law was also intended to attract foreign investment and facilitate the entry of technology into the country. However, it is also emphasized that efforts to develop an IP system, including patents, in Indonesia are not solely due to international pressure, but also because of the national need to create an effective IPR protection system. However, the 1989 Patent Law was revised in an effort to harmonize all laws and regulations in the IP sector with the TRIPS Agreement. The 1989 Patent Law was replaced by Law no. 13 of 1997 on Patents, to serve as the agenda for ratifying the TRIPs Agreement/WTO.[39] In 2001 the Government of Indonesia passed Law no. 14 of 2001 on Patents to revise the previous Patent Law. In 2001 the Government of Indonesia passed Law no. 14 of 2001 on Patents to revise the previous Patent Law. Until now the Patent Law has been revised through Law no. 13 of 2016 concerning Patents.

On October 5, 2020, the Government together with the House of Representatives The Republic of Indonesia (DPR RI) has ratified the Draft Law on Job Creation which later became Law No. 11 of 2020 concerning Job Creation (UU Ciptaker). The Copyright Law, in addition to changing provisions related to 11 clusters related to job creation, also changes provisions related to Patents through Article 107 of the Copyright Law. The following are 6 (six) changes to the Patent Law in the Copyright Law.

1.4. Legal Regulations to Regulate the Protection of the Covid-19 Vaccine Through Patents for the Public Interest

Protection against the Covid-19 vaccine is a problem and a study that will be widely discussed. This is considering that various countries and the private sector are competing in developing a COVID-19 vaccines. The inventor of the vaccine for the first time can of course get exclusive rights to his invention and close the opportunity for other parties to get the same rights. Ownership of patent rights makes a person have economic rights and moral rights over the inventions he has created. Patent rights able to protect the know-how of invention which never invented before. This thing make patent correlates with trade secret as well in regards that the trade secret is also consisted of technology and commercial element that shall be protected.[40] TRIPS is the first international convention to establish rules related to the protection of trade secrets. TRIPS says in order to ensure effective protection against unhealthy competition as referred to in Article 10bis of the Convention Paris, one can prevent trade secrets (referred to as confidential information in the agreement), from being disclosed, shared, or used by another party without his consent in a way that is contrary to honest trading practice (Article 39(2)). TRIPS too stipulates that data relating to pharmaceutical products supplied to the government must also be protected such as trade secrets (Article 39 (3)).[41] In the matter of Intellectual property rights, basically, any inventor is able to choose to protect their invention through patent rights or trade secrets.[42] There are several differences and risks to choosing protection through patent rights and trade secrets. First, patent rights have a limited period of time in accordance with the protection.[43] Meanwhile, a trade secret does not have a limited period of protection time as long as the trade secret does not undisclosed to the public.[44] Then, the form of the patent object is something that must be able to be written, drawn, or registered based on a stipulation in the Directorate of IPR.[45] Different from a patent, a trade secret

[39] Endang Purwaningsih, *Hak Kekayaan Intelektual dan Lisensi*, Bandung: Mandar Maju, 2012, p 61.
[40] Besar, "Hukum Kekayaan Intelektual", in *Aspek Hukum Ekonomi dan Bisnis*, compiled by Shidarta (eds), Jakarta: Prenada Media Group, 2018, p 92.
[41] Reza Zaki, *Hukum Perdagangan Internasional*, Jakarta: Prenada Media Group, 2021, p. 149
[42] Endang Purnawingsih, *Op.Cit.*, p. 96
[43] *Ibid.*
[44] *Ibid*.
[45] *Ibid.*

does not necessarily have to be written or noted.[46] Further, Trade secret object protection is not necessary to something that contains an invention or certain creativity,[47] but a patent shall contain an invention that was never invented before. Therefore, there are some risks and considerations to choose protection through patents or trade secrets.

However, in this matter, the researchers would like to emphasize if the legal protection of vaccines are protected through patens rights. With the ownership of the patent, the owner has the opportunity to monopolize his invention. Of course, this is not a problem when the inventions are not related to the safety of a person's life, but this is different from the current world situation where there is an urgent need for vaccines. As is well known, President Joko Widodo has issued Presidential Decree No. 12 of 2020 concerning the Determination of Non-Natural Disasters Spreading Covid-10 as a National Disaster. This reflects that the situation in Indonesia is experiencing a state of emergency, namely an unexpected difficult (difficult) situation (in danger, hunger, etc.) that requires immediate response. This patent right will be vulnerable to commercialization and make access to this covid-19 vaccine only accessible to a few people, especially those with financial capabilities. Globally, the regulation of patent rights is regulated in the Trade-Related Aspects of Intellectual Property Rights which is a milestone in the protection of patents worldwide. In Indonesia itself, the regulation of patents is regulated in Law no. 13 of 2016 concerning Patents.

1.5. Regulations Regarding Patents in the Paris Convention, TRIPs Agreement, Patent Law, and Job Creation Law

As explained above, a patent is simply a right to protect an invention of an inventor in the field of technology within a certain period of time, which is granted by the government to be used by himself or by others with the permission of the inventor. The reason an invention is protected is intended to encourage innovation and the implementation of the transfer of technology for mutual benefit in a way that is conducive to welfare and social welfare, as well as with a balance of rights and obligations (Article 7 TRIPS Agreement). The patent protection system provides the possibility of of emerging new technological inventions from previously known inventions with an associated set of cost and return probabilities.[48]

Patent arrangements are scattered in various state conventions. One of the general patent arrangements is regulated through the TRIPs Agreement and the Paris Convention. The TRIPS Agreement itself regulates intellectual property as a whole such as regulating copyrights, industrial designs, and so on. So it can be said that the TRIPs Agreement does not only regulate patents specifically. Specific conventions governing patents are agreed through the Paris Convention.

The Paris Convention aims to harmonize the industrial property about protection between countries. However, the Paris Convention does not rule out the possibility if there are countries that want to regulate the property industry specifically through agreements between countries. The Paris Convention itself has set the foundation for the industrial property protection. Like the first, there is a scope of property industry objects regulated in the convention, not only patent objects but also usability models, industrial designs, and trademarks, service marks, and other related property industries. Then in Article 1 paragraph 4 of the Paris Convention it is explained that the scope of patents is based on

[46] *Ibid.*
[47] *Ibid.*
[48] Edmund W. Kitch, "The Nature and Function of the Patent System", *The Journal of Law and Economics*, Vol. 20, No. 2, 1977, p. 266

existing laws in the territory of the country, such as import patents, improvement patents, additional patents and certificates, and so on.

Then Article 2 of the Paris Convention also emphasizes equality between citizens in countries that have agreed to the Paris Convention in order to get protection and access to the same legal remedies even though the status of the citizen is not a citizen of the country where the patent is registered. Even in Article 3 of the Paris Convention, the rights of citizens who have not agreed to the Paris Convention must still receive the same treatment as other member countries. Then even though the arrangements related to patents are agreed internationally, their validity remains territorial, as described in Article 4bis paragraph (1). So that to be valid in another country, a patent must be registered in that other country, with priority rights and having the same protection period as the place where the patent was first registered. Then the Paris Convention also regulates the rights of the inventor, namely the right to mention his name in the patent (Article 4). In addition, the Paris Convention also prohibits that a patent application may not be rejected on the grounds that the patent was obtained through a patented process that is subject to restrictions resulting from domestic law. Then the Paris Convention also provides a provision that each country has the authority to regulate compulsory licenses through the legislation process to anticipate the misuse of patents owned by license holders (Article 5 paragraph 3). Even if the granting of a Compulsory License cannot prevent the patent holder's misuse, the patent can be revoked, provided that 2 years have passed from the issuance of the compulsory license. The nature of the compulsory license regulated in the Paris Convention itself is that it must be non-exclusive and non-transferable, and must be executed within 4 years of the patent application or 3 years after the patent is granted (Article 5 paragraph 4). However, the provisions that apply to Article 5 paragraph 4 are mutatis mutandis whose meaning may change depending on the circumstances.

The TRIPS Agreement is the parent of the overall protection of Intellectual Property (Minimum Principles). The purpose of providing this protection is to stimulate the birth of new inventions, as well as the distribution of technology in a manner conducive to social and economic welfare (the principle of commercialization and technology transfer), as well as by maintaining a balance between the rights and obligations of the licensee and the user of the invention (Article 7 TRIPS Agreement). This shows the principle of commercialization of intellectual property and technology transfer. However, to understand the TRIPS Agreement, member countries must also comply with and apply conventions related to the protection of other intellectual property, in terms of patent protection, they must understand and apply the Paris Convention (Article 1 point 3). This shows the existence of the Full Compliance Principle as described in Article 1 of the TRIPs Agreement. However, in it is application, the TRIPS Agreement is not an agreement that specifically regulates patents, but complements and harmonizes the provisions of Intellectual Property protection, one of which is related to patents.

The TRIPS Agreement required all members to apply the provisions contained in the TRIPS Agreement and even allow them to expand these provisions as long as they do not conflict with the basics specified in the TRIPS Agreement (Article 1 point 1 and number 2). Actually, the TRIPs Agreement also gives authority to member states in terms of drafting or changing laws, in order to maintain nutrition and public health and to assist in realizing important interests in the social sector (Article 8 point 1). Although it has a commercial purpose, TRIPs Agreement prioritizes the principle of public interest. This is possible in order to keep intellectual property from being misused so that it has a negative impact. However, the conditions that do not conflict with the TRIPs Agreement are a requirement that cannot be compromised. It is the same as regulated in the Paris Convention and other intellectual property protection conventions, that every member country in the TRIPS Agreement must give equal rights to everyone even though they are not citizens of a member country (Article 3 of the

TRIPS Agreement). The rights of each person must be granted immediately without any special conditions. This provision embeds the principle of equality in rights and the principle of non-discrimination in the TRIPs Agreement.

It is the same with the Paris Convention, although the arrangements related to intellectual property have been agreed internationally, but it is validity is within the territorial scope of a member state itself (territorial principle). This territorial principle becomes important in terms of recognizing the sovereignty of a country in enforcing the law. Law enforcement related to patents in a country will also be clearer with the existence of this territorial principle, although it may be that the same invention is registered in different countries. In Indonesia, patent protection has existed since before Indonesia's independence. The history of patent regulation in Indonesia has emerged since the era before Indonesia's independence, where during the colonial period Indonesia had been a member of the Paris Convention for the Protection since 1888. 33 yis S 11-136, S 22-54. During the Japanese occupation in 1942 s.d. 1945, all laws and regulations in the field of Intellectual Property Rights remain in effect. At the time of Indonesia's independence, all laws that did not conflict with the 1945 Constitution remained in effect. The Patent Law became a regulation that was sacrificed because it was considered contrary to the 1945 Constitution. The reason the patent provision was revoked was because it was contrary to the Sovereignty of the Republic of Indonesia, precisely because the mechanism for registering the patent had to be submitted to the Netherlands.[49]

In 1988 based on Presidential Decree No. 32 it was stipulated that the Directorate General of Copyright, Patents and Marks (DJ HCPM) be established to take over the functions and duties of the Directorate of Patents and Copyrights, which is one of the echelon II units within the Directorate General of Law and Legislation, Ministry of Justice. Then on October 13, 1989, the House of Representatives approved the Bill on Patents which was later ratified by the President on November 1, 1989. The law was numbered as Law No. 6 of 1989 (Patent Law 1989). The purpose of the ratification of the 1989 Patent Law is to provide legal protection and to realize a legal protection for the technology industry, especially related to inventions. The ratification of the 1989 Patent Law was also intended for a country to attract foreign investment and facilitate the entry of technology by the other country. However, it is also emphasized that efforts to develop an IP system, including patents, in Indonesia are not solely due to international pressure, but also because of the national need to create an effective IPR protection system. However, the 1989 Patent Law was revised to harmonize and to effort all laws and regulations in the IP sector with the TRIPS Agreement. The 1989 Patent Law was replaced by Law no. 13 of 1997 concerning Patents, to serve as the agenda for ratifying the TRIPs Agreement/WTO. In 2001 the Government of Indonesia passed Law no. 14 of 2001 concerning Patents to revise the previous Patent Law until now the Patent Law has been revised through Law no. 13 of 2016 concerning Patents.

On October 5, 2020 the Government together with the House of Representatives The Republic of Indonesia (DPR RI) has ratified the Draft Law on Job Creation which later became Law No. 11 of 2020 concerning Job Creation (UU Ciptaker). The Copyright Law, in addition to changing provisions related to 11 clusters related to job creation, also changes provisions related to Patents through Article 107 of the Copyright Law. To examine the existing patent protection in Indonesia, here the researcher will provide an overview of the provisions related to patents that have been amended in the Copyright Act, so that the discussion can be interpreted comprehensively in the midst of the situation of the Copyright Law which has just been inaugurated.

[49] Handaya Surya Wibawa, *Op.Cit.*, p. 84

Although only 6 Articles of the Patent Law have been amended, they have a significant impact on patent provisions in Indonesia. Such as related to patent applications which have become shorter, to the form of patent implementation that has changed. The amendment to Article 20 regarding the implementation of patents contradicts the nature of the purpose of implementing patents which puts forward the principle of transfer of technology. At present, import activities are considered as the implementation of patents, so that foreign license holders in particular do not need to build factories that can absorb various jobs. But on the other hand, it can actually make it easier for Indonesia to get access to the Covid-19 vaccine because foreign countries don't need to build a vaccine factory in Indonesia so they can reduce their costs to get the vaccine market in Indonesia.

1.6. Provisions for the Implementation of Covid-19 Vaccine Patents by the Government

The patents implementation by the government is not a foreign practice because Indonesia applies it when facing the HIV and AIDS epidemic. But that does not mean that what the government is doing is an arbitrary act that violates the law or exceeds the limit. The patents implementationby the government itself has been agreed in the TRIPs Agreement which is a legal source of intellectual property which has also been adapted, one of them by the Indonesian government. The regulation on the implementation of patents by the government has been agreed upon in Article 31 of the TRIPs Agreement as written in the following table:

Table 1. TRIPS Agreement

TRIPS Agreement
Article 31 Other Use Without Authorization of the Right Holder Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: (a) authorization of such use shall be considered on it is 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 non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of 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;

Article 31 of the TRIPs Agreement regulates the exclusion of patent protection. As we know that if you want to implement a patent, you must get approval from the license holder. Article 31 letter (b) of the TRIPs Agreement, stipulates that the government can implement a patent without the permission of the patent holder on the condition that the government has tried to obtain permission from the license holder, but the negotiations are unsuccessful within a reasonable time.

This is illustrated in the sentence:

"*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.*"

Use of an invention without the patent holder's permission is only permitted if there have been attempts to seek approval from the licensee under commercial terms and conditions, but these have failed within a reasonable effort timeframe.

However, if we examine these efforts, it will take a long time, moreover, time phrases that are considered reasonable will become polemics that will lead to new problems. Therefore, in the next sentence, the TRIPs Agreement provides for an exception to the obligation that the government must make efforts to implement patents as regulated below:

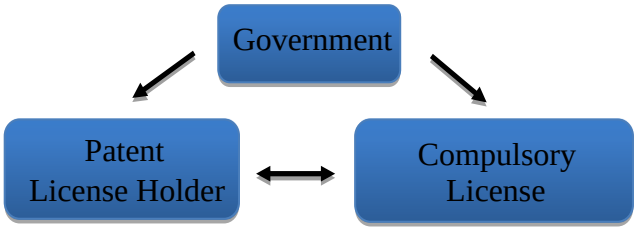
"*This requirement may be waived by a member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of 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*."

Indonesia has also adopted this provision through the Indonesia Patent Law and President Regulation No. 77 of 2020 concerning the Implementation of Patents by the Government. Thus, the Government of Indonesia has the authority to implement Covid-19 vaccines without the permission of patent rights holders in accordance with laws and regulations.

2. Dispute Settlement

2.1. Dispute Settlement in the Case of a Covid 19 Vaccine Patent Claim Between the Exclusive Patent Rights Holder and the State

In the implementation of patents by the government, the implementation is carried out when the patent holder no longer wants to produce his invention. Therefore, in the case needs of the public interest, the government can implement the invention by issuing a mandatory license (Article 82 of the 2016 Patent Law), which appoints a party as the licensee to produce the invention. Later the licensee is required to provide proper compensation to the patent holder as compensation. This implementation has the potential to cause disputes when there are patent holders who do not approve of the issuance of a mandatory license by the government, and/or compensation provided by the licensee to the patent holder. Therefore, disputes in legal relations are common and often occur. Differences in understanding, interests, non-fulfillment of rights and obligations are examples that cause a dispute to arise.



Picture 1. Legal Relations Scheme in the Implementation of Covid-19 Patents

1. Standard explanation of the relationship between the government and patent holders:
   A patent holder who no longer wants to apply for a patent, the government can apply for a patent. The patent holder can refuse by filing a lawsuit through the commercial court (Article 87, Article, 89 Article, and Article 103 of the 2016 Patent Law).
2. Standard explanation of the relationship between the government and the recipient of a compulsory license The government can implement a patent by appointing a recipient of a compulsory license appointed by the government. Recipients of compulsory licenses must carry out the mandate given by the government by carrying out their obligations to implement patents.
3. Standard explanation of the relationship between compulsory license and patent holder

Recipients of mandatory licenses appointed by the government are required to provide appropriate compensation based on economic value to patent holders (Article 27 Regulation of the Minister of Law and Human Rights of the Republic of Indonesia Number 30 of 2019 concerning Procedures for Granting a Compulsory Patent License (Permenkumham 30/2019)). Patent holders who do not agree to the compensation provided can file a lawsuit through the commercial court (Article 28 of Permenkumham 30/2019).

In relation to the implementation of the COVID-19 vaccine patent for the public interest, there are possibilities of disputes between the government and license holders that could occur, including:

1. License holder objected to government issuance of compulsory license
2. The licensee must not exercise his rights and obligations
3. Licensees are not properly compensated
4. License holders are not compensated

2.2. Settlement Through Litigation

Patent provisions in Indonesia require that disputes be resolved through litigation. The commercial court is a court that has competence in resolving disputes through litigation. Here the researcher has collected a table of articles that require that they be able to resolve disputes through litigation.

Table 2. Law No. 13 of 2016 concerning Patent

Patent Law
Article 89 Decision of the Minister on the granting of a compulsory License as referred to in Article 88 section (1) may be a subject of a lawsuit to the Commercial Court.
Article 117 (1) In the event that the Patent Holder does not agree with the amount of Remuneration given by the Government as referred to in Article 115, the Patent Holder may file a lawsuit to the Commercial Court. (2) The lawsuit as referred to in section (1) may be submitted within the period of 90 (ninety) Days as from the date that a copy of Presidential Regulation as referred to in Article 109 section (3) is sent. (3) In the event that the Patent Holder does not file lawsuit as referred to in section (1), the Patent Holder is deemed to agree on the amount of Remuneration (4) The process in examining the lawsuit as referred to in section (1) does not cease the Government use of Patent.

Article 143

(1) The Patent Holder or Licensee is entitled to file a lawsuit for damages through the Commercial Court against any Person who deliberately and without authorization performs any acts as referred to in Article 19 section (1).

(2) The lawsuit for damages filed against any acts as referred to in section (1) may only be accepted if the product or process is proven to have been produced by using the Patented Invention.

Article 153

(1) Besides dispute settlement as referred to in Article 143, the parties may settle a dispute through arbitration or alternative dispute settlement.

(2) Dispute settlement using arbitration or alternative dispute settlement is performed in accordance with the provisions of prevailing legislation.

Article 154

In the event of criminal prosecution against Patent or simple Patent infringement, all parties must beforehand take mediation.

The mechanism for resolving disputes related to the implementation of patents by the government has been accommodated by the existing laws and regulations in Indonesia. For example, if a patent dispute arises regarding the calculation and determination of the amount of patent compensation due to the implementation of a patent by the government, the licensee can file a lawsuit to the commercial court (Article 117 paragraph (1) of the Patent Law). The time limit for the lawsuit is given a period of 90 (ninety) days (Article 117 paragraph (2) of the Patent Law). The consequence is that if the patent holder does not file a lawsuit, the patent holder is considered to have agreed to the amount of compensation that has been given by the government (Article 117 paragraph (3) of the Patent Law).

2.3. Settlement Through Non-Litigation Law No. 30/1999 on Arbitration and Alternative Dispute Resolution

In addition to patent disputes that can be done through litigation, there are other alternative dispute resolutions. Settlement of patent disputes through alternative dispute resolution is explained in Article 153 of the Patent Law. Alternative dispute resolution routes that can be taken include negotiation, conciliation, arbitration, mediation, consultation, or expert judgment. To be able to resolve disputes through Arbitration, the provisions are explained in Article 1 number 10 of the Arbitration Law and Alternative Dispute Resolution.

The explanation of Arbitration in general has been explained in the Arbitration and ADR Law. Arbitration in the field of intellectual property aims to help resolve issues related to intellectual property amidst the increasing commercialization of intellectual property assets on the basis of higher economic interests. Arbitration settlement in the field of intellectual property rights is important because arbitration disputes have sensitive links related to technical and business information.[50] The closed nature of arbitration can provide a sense of security to the disputing parties, especially to protect the know-how of the invention product.

The definition of arbitration itself is a way of settling a civil dispute outside the general court based on an arbitration agreement made in writing by the disputing parties (Article 1 point 1 of the

[50] Christopher Book & James Menz, "Arbitrating IP Disputes: the 2014 WIPO Arbitration Rules", *Journal of Arbitration Studies*, Vol. 24, No.3, 2014, p.12.

Arbitration and ADR Law). Therefore, to be able to resolve disputes through arbitration, there must be an arbitration agreement agreed upon by the disputing parties. The parties themselves can choose the arbitrator, choice of law, and choice of forum in the agreement. The chosen arbitration institution and APS can be carried out in all existing arbitration institutions and APS throughout the world, as long as the country in which the institution is based has agreed to the 1958 New York Convention. Thus, the award of arbitration institution from across the country can be executed in Indonesia as long as the origin country of arbitration institution is bound to the New York Convention. However, the output of the dispute resolution, especially the arbitration decision, cannot be carried out if the panel of judges cannot find the benefits of the decision, it is contrary to the public interest, and other reasons regulated in the legislation. The burden of proof in refusing the implementation of the foreign arbitral award is borne by the defendant in the disputing parties.

The parties who have made an arbitration agreement will eliminate the competence of the court to be able to handle the case submitted (Article 3 of the Arbitration and ADR Law). It is just that civil cases that can be submitted to arbitration are not civil as a whole, but only disputes in the trade sector and regarding rights which according to law and legislation are fully controlled by the disputing parties (Article 5 of the Arbitration and ADR Law).

Types of subjects that can resolve disputes include legal subjects within the scope of civil law and public law (Article 1 point 2 of the Arbitration and ADR Law). So that in this case the dispute resolution between the patent holder as a legal subject in the civil scope, and the government as a legal subject in the public sphere can be resolved through arbitration. Later the dispute resolution through arbitration will be assisted by the Arbitrator as one or more chosen by the disputing parties, the district court, or by the arbitration institution (Article 1 point 7 of the Arbitration and ADR Law). The task of the arbitrator himself is to give a decision regarding certain submitted disputes (Article 1 point 7 of the Arbitration and ADR Law).

The disputing parties can also choose an arbitration institution as the institution that will give a decision regarding a particular dispute; the institution can also provide a binding opinion regarding a certain legal relationship in the event that a dispute has not arisen (Article 1 point 8 of the Arbitration and ADR Law). In resolving disputes through arbitration, it is known as an International Arbitration Award, namely a decision handed down by an arbitration institution or an individual arbitrator outside the jurisdiction of the Republic of Indonesia, or a decision by an arbitration institution or an individual arbitrator which according to legal provisions is considered an international arbitration award (Article 1 point 10). In Indonesia there is an institution that provide dispute resolution forum especially on IPR. The institution provides dispute resolution through arbitration or ADR forum and knowingly as *Badan Arbitrase dan Mediasi Hak Kekayaan Intelektual* (Arbitration and Mediation Institution of Intellectual Property Rights) or BAM HKI. In order to settle the dispute in BAM HKI, the parties shall make a written arbitration agreement and the dispute later will be settled based on BAM HKI Procedural and Arbitration and ADR Law.[51] A few of the several reasons BAM HKI are established in Indonesia are the increasing of IPR protection and in order to empower law enforcement on Intellectual Property Rights in Indonesia, as all this time is being the critic to Indonesia law enforcement on IPR.[52]

[51] Grace Henni Tampongangoy, "Arbitrase Merupakan Upaya Hukum Dalam Penyelesaian Sengketa Dagang Internasional", *Lex et Societatis*, Vol. 3, No.1, 2015, p. 168.
[52] *Ibid.*

III. CONCLUSION

Based on the explanation of the study that has been described, the researcher concludes as follows:

1. The exclusive rights of the patent holder are protected from the TRIPS Agreement, the Paris Convention, the Patent Law, and Presidential Decree 77/2020. The patent holder has the monopoly right to allow or prohibit someone from exercising the patent. However, in a state of urgency or a national disaster, the government can issue a mandatory license to maintain public health. In order to maintain the patent ecosystem, in exchange for the licensee appointed by the government, it is obligatory to provide proper compensation to the patent holder. This concept is regulated in Article 31 of the TRIPs Agreement, while in positive Indonesian law it is regulated in Article 93, Article 97, Article 98, Article 99, Article 101, Article 102, Article 103, Article 106, Article 109, and Article 111 of the Patent Law. . In addition to being regulated in the Patent Law, the implementation of patents by the government is also emphasized through Presidential Decree 77/2020.
2. Settlement of patent disputes against Covid-19 vaccine patent holders can be resolved through litigation and non-litigation. Within the scope of compensation disputes, or related to the issuance of mandatory licenses, it can be resolved through a commercial court. However, in principle, dispute resolution related to patents should be prioritized through Alternative Dispute Resolution (ADR) channels, such as through BAM HKI. Patent disputes of a technical nature consisting of confidential information will be more profitable if resolved through the ADR channel. Because apart from being secretive which keeps important secrets from the parties, settlement through the APS channel is considered more efficient and effective. This is because there is a shorter period of time than going through the courts, and the dispute resolution can be assisted by an experienced third party. With the assistance of an experienced third party, the appointed party must understand the technicalities related to patents and be able to provide solutions for the disputing parties. Although basically the settlement of patent disputes can be resolved through other ADR institutions such as the WIPO Center, it would be better if the parties to the dispute in Indonesian territory could resolve disputes in institutions in Indonesia such as BAM HKI. This is to support and realize the enforcement of intellectual property rights in Indonesia, as well as the existence of BAM HKI both in Indonesia and in the eyes of the international community.

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