DISCUSSION ANALYSIS OF ABOLISHING PATENT RIGHTS FOR COVID-19 VACCINE

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<th><strong>ABSTRACT</strong></th>
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<td>This study outlines the emergence of discourse in the discourse of the abolition of the Covid-19 vaccine patent which is currently developing in a number of countries. On the one hand, those who are pro against the discourse have a number of arguments that underlie this view, such as the urgency of the need for massive and rapid vaccine production and on the pretext of ensuring global health aspects. Then on the other hand, those who are against it think that the discourse on the abolition of the Covid-19 vaccine patent is not the right solution because it is feared that it will cause disappointment from pharmaceutical companies and related parties and because this is an aspect that is the responsibility of the state and has been regulated in legal instruments in the field of intellectual property. Meanwhile, the theoretical perspective used refers to the discourse theory proposed by Ernesto Laclau and Chantal Mouffe. In addition, the research method referred to is a qualitative method using a literature study technique on related scientific sources.</td>
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**KEYWORDS**


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INTRODUCTION

In late December 2019, a mysterious outbreak of pneumonia characterized by fever, dry cough, and fatigue, and occasional gastrointestinal symptoms occurred at the Huanan Seafood Wholesale Market, in Wuhan, Hubei, China (Huang, Wang, Li, Ren...
Zhao, Hu, et al. The initial incident reportedly originated in the market in December 2019 and involved around 66% of the staff there. The market was then closed on January 1, 2020, following the announcement of an epidemiological warning by local health authorities on December 31, 2019. However, the following month (January) thousands of people in China, including other provinces such as Hubei, Zhejiang, Guangdong, Henan, Hunan and Beijing and Shanghai was attacked with similar symptoms that are increasingly rampant. The pathogen of the outbreak was later identified as a new beta-coronavirus, named 2019 novel coronavirus (2019-nCoV) and the World Health Organization (WHO) referred to it as Corona Virus Disease 2019 (COVID-19) and brings to mind the terrible memory of acute respiratory syndrome severe (SARS-2003, caused by another beta-coronavirus) that occurred 19 years ago.

Meanwhile, the emergence of the SARS-CoV-2 virus in December 2019 in the Wuhan area, China can be said to have had its own impact on global community civilization. This then prompted the World Health Organization (WHO) to designate the virus as a global pandemic on March 11, 2020 after successfully spreading to 114 countries. Meanwhile, the virus was then temporarily named by WHO as a severe acute respiratory disease 2019-nCov. Until finally, WHO, as stated by Director General Tedros Adhanom Ghebreyesus at a press conference in Geneva, Switzerland, then replaced it with a new term, namely Covid-19. In this case, the term "co" itself refers to the name Corona, "vi" means virus, "d" is disease (disease) and 2019 is the year when the virus began to appear for the first time.

Although the exact origin, location and natural reservoir of 2019-nCoV is still unclear, many believe that the virus is zoonotic and that bats may be the culprits because bats are considered the natural host reservoir of the SARS-like coronavirus (Perlman, 2020). Theoretically, if people contact or eat infected reservoirs or animals, they could become infected. The National Health Commission of China is examining and developing methods to identify new COVID-19 cases, as there is growing evidence that transmission is also occurring in groups of people who have never been to the Hunan Seafood Wholesale Market. This shows that the corona virus spreads from person to person through direct contact with an infected person through the air inhaled from coughing or sneezing. Because the coronavirus is so small, it is difficult to detect its spread in the first place. Fever, chills, cough, fatigue, and shortness of breath are the first symptoms shown by COVID-19. The virus then targets the lungs, resulting in moderate or acute pneumonia, lung pneumonia, respiratory damage or failure, and ultimately death.

Due to the movement of people from one location to another, the corona virus continues to spread massively and uncontrollably. The COVID-19 outbreak has spread to other countries, such as Thailand, Japan, the Republic of Korea, Vietnam, Germany, the United States, and Singapore and even almost every country on the planet, and on March 11, 2020, Dr. Tedros Adhanom Ghebreyesus in his speech, determined that COVID-19 was declared a pandemic (World Health Organization, 2020a). With this condition, the role and contribution of the government and all countries in the world are needed to carry out control efforts so that the spread of COVID-19 does not expand and take more victims. China, as the initial location for the spread of COVID-19, stipulates policies to restrict human movement, travel restrictions, closures, tracing and monitoring a person's health/travel history, to the implementation of quarantine on individuals. In the United States, the government urges its citizens to wear masks, enforce social distancing, prohibits its citizens from gathering and partying, to closing schools and other public facilities. Indonesia has also implemented similar policies, ranging from implementing social and physical distancing, implementing Large-Scale Social Restrictions (PSBB) to issuing policies to carry out activities online.
The COVID-19 pandemic has brought together the countries of the world to solve this problem and also discuss preventing similar things from happening in the future. The option to create an effective COVID-19 vaccine is a priority when that. In addition, there is also a priority to ensure that the vaccine is given fairly and equitably to everyone. Vaccines have been proven to save millions of people from infectious diseases. Vaccines work naturally to train and prepare the immune system to fight and kill viruses, bacteria, and germs that infect the body and prevent disease (World Health Organization, 2020).

Then after the reactivation of the Research & Development Blueprint by WHO, to strengthen its role in accelerating the development and equitable access to vaccines, diagnostics, and treatment of COVID-19, various countries and pharmaceutical companies such as Moderna, CanSino Biologics China, Oxford University-AstraZeneca, Pfizer are competing -the race to find a COVID-19 vaccine and conduct clinical trials. The race to develop a COVID-19 vaccine is not only based on global public health interests but also a race for ownership rights to the invention, also known as a "patent". Patent is the protection of Intellectual Property Rights (IPR) which is given to inventors for their processes or findings as a form of appreciation for intellectuality for creating a new work or invention. It is natural that the inventor or inventor of the COVID-19 vaccine is given protection against the results and process of finding a COVID-19 vaccine. This is done to encourage inventors to continue to innovate and make new findings. With the current state of the COVID-19 pandemic sweeping the world, the reality of the world's patent system, both registration and patent protection, has not set boundaries for emergency situations, especially for vaccines and medical devices. Thus, if a vaccine or medical device meets the basic criteria, which are novelty, contains an inventive step and can be applied in the industry (industrial applicable), then the product can be patented which has actually been mandated in Law No. 13 of 2016 concerning Patents. With this process, the patent holder gets the exclusive right to the patent, even though the vaccine is currently being needed by people around the world.

In the case of granting patent rights to COVID-19 vaccine inventors, there will be a conflict of interest between the patent rights granted as an award and protection from the inventor or patent holder and urgent needs on behalf of global public health. The motivation to make as much profit as possible is an important variable for the availability of a COVID-19 vaccine in the future, considering that the research, development and clinical trials process costs money, time and energy from researchers. Developed countries will be at the forefront to continue to conduct research and development of COVID-19 vaccines, invest and lobby to ensure vaccine availability for their citizens, including entering into vaccine pre-production agreements with leading pharmaceutical companies. Therefore, the priority to ensure the availability of vaccines for all people from developed, developing and least developed countries (LDCs) is important. This means that the COVID-19 vaccine must be mass-available and the price must be affordable. This conflict of interest must be carefully considered by policy makers. The policies taken must of course be fair and wise, so that the policies taken do not conflict with the rules and provisions of the patent law but also prioritize the public interest of the community.

**RESEARCH METHOD**

This study uses content analysis with qualitative research methods. Qualitative research methods are research methods that emphasize words and the values they contain. One of the analytical models used to review content is discourse analysis. Discourse analysis is an analysis of speech and other forms of discourse that emphasizes how the
meaning of reality occurs through a language because it is considered to regulate and produce the social world (Bryman, 2016). The analyzed discourse is obtained from existing sources or data obtained without direct research. The data studied are secondary data, namely data obtained from existing sources or data obtained not through direct research. Secondary data that will be examined are documents, policy statements, press conferences, related newspaper articles.

Furthermore, discourse itself can be understood as a social construction in which each subject (subject position) gives meaning to an object or practice. For example, there are different views and meanings on the discourse on the abolition of the Covid-19 vaccine patent, which involves various parties. The meaning that is then formed through objects or actions occurs in a special construction system called the discursive arena. The discursive arena is an arena that is infinite and dynamic (Howarth, Norval, & Stavrakakis: 2000). The discursive arena can occur because the meaning is uncertain (contingent), not fixed, partial, relational, and never absolute. Meanwhile, Laclau and Mouffe explain three concepts in discourse theory: subject position and political subjectivity, antagonism, and hegemony. Subject position is the placement of the subject in the discursive arena. In this case, for example, there are groups that are for and against the implementation of the PSBB policy. Meanwhile, political subjectivity places great emphasis on how the subject acts. Laclau argues that the subject's actions arise due to a discursive arena that has uncertainty in it (there is room for debate) (Howarth, 1998).

In addition, Laclau and Mouffe (in Howarth, 1998) explain that antagonism is represented as a dispute between social agents/subjects who have a clear identity. Antagonism further refers to two opposing parties with an interest in killing each other (Hanif, 2007). This shows that antagonism is a threat to other identities. The construction of antagonism according to Laclau and Mouffe (in Howarth, 1998) is formed from the concept of logic of equivalence. Meanwhile, this then takes the example of the black movement in South Africa in the 1960-1970s. The concept basically explains that in discourse, groups will try to connect other groups (such as ethnicity, race, social class, gender, etc.) to fight the enemy of the discourse.

Subjects/agents who are antagonistic to each other in the discursive arena will compete to achieve hegemony. According to Laclau and Mouffe, hegemony is a form of political articulation that involves connecting various identities into one and then forming a social order from various divided elements. The practice of achieving hegemony requires two further possible conditions, namely the existence of antagonistic forces and the instability of the political boundaries that divide them. The main goal of achieving hegemony is to establish and stabilize what Laclau and Mouffe call a nodal point (Howarth, 1998). In this case, nodal point is defined as a special marker or reference point in a discourse that ties together a particular system of meaning or in other words a chain of significance (Howarth, Norval, & Stavrakakis, 2000: 8).

RESULT AND DISCUSSION

The COVID-19 vaccine, on the one hand is an economic commodity that needs protection from legal instruments, but on the other hand it is also a human right. It is important to examine the legal protection of the COVID-19 vaccine as intellectual property (IP) which is the work of human thought. Legal protection, as stated by Roscoe Pound, is that the law functions as a tool of social engineering which can be divided into three types of interests, namely: first, the interest of the state as a legal entity for the public interest. Second, the interests of the state as guardians of social interests (social interests). Third, the state's interest in the individual (private interest) (Tanya, 2010). In addition, there is a
view from Robert M. Sherwood who thinks that providing incentives to inventors will encourage the desire to produce other KI (incentive theory); appreciation of the effort, cost, time and thought that have been devoted to making inventions (recovery theory); and awarding inventors for their hard work (reward theory) (Sherwood, 2018). This theory can be used as the basis for protecting IPR against COVID-19 vaccine inventions.

Covid-19 vaccination is closely related to two ideas of legal protection as a means of protecting human rights in the public, social and private spheres. At the global level, intellectual property rights have been agreed upon through various conventions, such as the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) under the aegis of the World Intellectual Property Organization (WIPO), the Bern Convention 1886, and the Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) which is sheltered by the World Trade Organization (WTO). Article 27 paragraph (1) of the TRIPs Agreement states that the state is obliged to grant patents to inventors for inventions that are unique, innovative, and can be used in industry. In this case, the COVID-19 vaccine is an invention in the pharmaceutical sector that allows the protection of ownership rights.

Furthermore, the patent itself actually results in the emergence of exclusive rights, which also contain economic rights and moral rights for the owner. Article 28 paragraph (1) of the TRIPs Agreement states the exclusive rights granted to patent holders, namely:

a. If the object being patented is a product, then the patent provides protection for the right holder from the actions of third parties who make, use, offer for sale, sell, or import the product without the consent of the rights holder.

b. If the object being patented is a process, then the patent provides protection for the rights holder from the actions of third parties for the purpose of offering for sale, selling, or importing products that have been produced through the patented process without the consent of the rights holder.

Based on Article 33 of the TRIPs Agreement, exclusive rights have a period of 20 years from the date of receipt of the application or patent registration. Exclusive rights automatically give rise to a 'monopoly right' for the right holder to exercise the patent for a specified period of time. If the patent rights are not implemented in accordance with applicable regulations, the patent can be revoked, so that other parties or the general public can freely enjoy this invention without the consent of the rights holder. In Indonesia, the regulation of patent rights is regulated in Law Number 3 of 2016 concerning Patents (Patent Law). Article 1 point 1 of the Patent Law stipulates the definition of a patent, which 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. This definition is also in line with the understanding provided for in WIPO, namely the legally enforceable right granted to a person under the law to exclude others from certain actions in relation to explaining new inventions for a limited time and that exclusive rights are granted by government authorities to people who are entitled to apply as long as they meet the specified requirements.

In order to claim a patent for a COVID-19 vaccine, inventors must meet three main substantive requirements, namely, novelty, considering that COVID-19 disease is relatively new and vaccine development for the virus is still developing, so when a vaccine is found, it can be judged to have meet the requirements of novelty, which means that the vaccine invention differs from the previously disclosed technology; can be used in the industrial world (industrial applicability), that the COVID-19 vaccine is similar to other vaccines that can be mass-produced to meet demand; and the last one involves a new stage (inventive step), which shows that this is something virologists have never seen before.
Taking this into account, as a result, the COVID-19 vaccine has met substantive requirements and can be protected by the patent regime.

Almost every country, including Indonesia, has been hit by the COVID-19 pandemic. On this basis, Indonesia bears the responsibility to implement various initiatives, efforts and programs to address these problems. According to Peter Salim, legal science uses three terms to describe responsibilities, namely: liability, responsibility, and accountability. First, liability as a form of legal responsibility in the form of civil liability. Second, responsibility is defined as an activity carried out to respond to a problem or issue. Third, accountability, which is associated with financial issues or issues of trust in a financial institution. The responsibility of the Government of Indonesia (Pemri) in this case is included in the category of responsibility, namely ensuring that the needs of the COVID-19 vaccine for its citizens can be met.

As stated in the fourth paragraph of the Preamble to the 1945 Constitution of the Republic of Indonesia, the Government is responsible for protecting the entire Indonesian nation and the entire homeland of Indonesia, promoting public welfare, educating the nation's life, and participating in carrying out world order based on independence, eternal peace and justice. social justice. It is the task of the Government of the Republic of Indonesia to become difficult to meet the domestic COVID-19 vaccine needs, if the COVID-19 vaccine has been protected by IPR because IPR gives exclusive rights to rights holders. These exclusive rights will result in other people/parties who will make, use, sell, import, rent, deliver, or give for sale, must first obtain permission from the rights holder. IPR does not regulate exclusive rights indefinitely. In general, the exclusivity of IPR can be excluded in certain circumstances. The presence of the state in fulfilling these needs can exclude the exclusivity of IPR that has been protected, thus there is a chance that actually the exclusivity of IPR is not without limits, taking into account that all countries need a COVID-19 vaccine to combat this global pandemic. Although in principle there are reasons that cause IPR to be attached to COVID-19 vaccine inventors, under current conditions, exclusive rights to IPR can result in social injustice, can result in social injustice, especially where the public interest is at stake.

State intervention as a form of government responsibility in terms of patent protection, is through the application of compulsory licenses. A license is a power of attorney granted to a licensee by the right holder or patent owner as the licensor, where a license is a kind of written agreement that transfers the right to use a patent that is still protected for a certain period of time and is subject to certain limitations. There are two types of licenses, namely exclusive licenses which are granted to one licensee in one particular region, and non-exclusive licenses which are granted to several licensees in several different regions. Although in reality, the license is made and agreed by the parties which is carried out on a civil and cooperative relationship. This is different from a mandatory license, which is obtained by application of a third party to the authorized official (Directorate General of Intellectual Property Rights/DJHKI) to implement a patent; compulsory license is not a civil relationship. A compulsory license is an administrative undertaking that produces a license or obtains a permit from the DJHKI if the application is approved and accepted. This means that on the basis of public interest, third parties no longer need permission from the rights holder or patent owner to obtain a mandatory license, but what is needed is only the approval of the DJHKI.

Article 5 Paragraph (2) of the Paris Convention states that a compulsory license needs to be regulated, as a form of prevention in case of abuse of the implementation of exclusive rights by patent holders. However, the Paris Convention only recognizes compulsory licenses as “non-exclusive compulsory licenses,” which are not transferred.
This is also regulated in Article 81 of the Patent Law which states that a compulsory license is a mandatory non-exclusive license. Article 7 of TRIPs and considering paragraph 4 of the Preamble of TRIPs, states that a balance between rights and obligations cannot be achieved by reducing the rights of patent holders without adding an element of public interest. This means that the individual rights of the patent holder cannot be limited for the benefit of other individuals and only on the basis of the public interest, the application of a compulsory license can be justified. Mandatory licensing only can be given to the Government (or Government agencies or third parties who have a mandate from the state) and other third parties (individuals) (Priapantja, 2003).

Applications for compulsory licenses by the government or third parties cannot be granted immediately, but only for special reasons, such as urgent needs of a country, other extreme situations and conditions, or public interests that are not for commercial purposes; as a preventive measure if the patent holder or licensee runs the patent in a form and manner that is detrimental to the public interest; as an effort to produce pharmaceutical goods that obtain patents in Indonesia for the treatment of diseases in humans; and as an effort to import pharmaceutical goods that are patented in Indonesia for the treatment of diseases in humans but cannot be produced in Indonesia. The reasons mentioned above can of course be used to justify state intervention in carrying out state responsibilities as a form of state presence in fighting COVID-19 through the use of mandatory licenses. In such cases, the responsibility of the state to fulfill state objectives through state actions is non-negotiable, especially as a compulsory license applicant if Indonesia is the recipient of the license. This is in accordance with Article 8 of TRIPs, which stipulates that member states may adopt or amend their laws and regulations to determine the necessary public health protection measures. The use of mandatory patent licenses in the pharmaceutical sector (in this case the COVID-19 vaccine) makes it easier to gain access to vaccines from developed countries/producers at more affordable prices (Dewi & Suteki, 2017). The most important thing is to ensure that the application of the mandatory patent license is based on the public interest even though the policy is forced to sacrifice the economic interests of the individual patent holder.

In addition to the mandatory patent license, to make exceptions to patent rights, the government can also apply for patents (government use). The Government use clause allows WTO member countries that are automatically subject to the TRIPs Agreement to use patents without permission from the patent holder, for reasons of certain circumstances such as protection of the public interest. Although there are similarities between the concept of compulsory licensing and government use, which aims to apply exceptions to exclusive patent rights, government use requires fair payments of royalties to patent holders. So far, government use is usually carried out in terms of drugs, namely to produce generic drugs. Where the main goal is to reduce production costs. So that drug distribution becomes easier and accessible to all circles of society.

The practice of government use can also be used as an option to apply for a COVID-19 vaccine invention patent, with the aim of accelerating access to vaccines for people who are within the jurisdiction of the government. When viewed from the production cost, the advantage will be seen in the availability of the COVID-19 vaccine at a reasonable price, but the quality and safety of the vaccine will be threatened given the main goal is to produce cheap vaccines. Especially if the use of government is implemented by developing countries, which are limited in the production and development of COVID-19 vaccines due to inadequate technology and funding sources.

WHO targets 70% of the global population to be vaccinated against COVID-19 by September 2022. The G20 Forum also supports achieving this target. In March 2021, the Organization for Economic Co-operation and Development (OECD) estimated that high-
Income countries, which make up 16% of the global population, had negotiated a supply agreement for a COVID-19 vaccine that accounts for about half of the world's supply. certainty of which vaccines are effective and get approval. Since the discovery of the COVID-19 vaccine to date, the purchase and production of COVID-19 vaccines has been dominated by rich economies/developed countries as vaccine-producing countries. As of April 4, 2022, only 12% of people in low-income countries, such as countries in Africa, were fully vaccinated (receiving two doses or one dose of a one-dose vaccine). It is very unfair when compared to the 74% of people who are fully vaccinated in high-income countries.

Inequality of access to the COVID-19 vaccine has become a concern for all countries in the world and has sparked a discussion on the abolition of COVID-19 vaccine patents. From the results of the discussion and discussion, developed countries are driving the donation of COVID-19 vaccines for developing countries and LDCs. The G7, which includes the UK, United States (US), France, Germany, Italy, Japan, Canada and the EU, is committed to donate 1 billion vaccines by June 2022. Additionally, through the Covax facility, a global vaccine-sharing initiative run by WHO and others, it has delivered free vaccines to low-income countries since February 2021. Its efforts are supported by vaccine donations and major financial assistance from G7 countries. With the various efforts that have been made, in fact developed countries and LDCs are still difficult to get access to the COVID-19 vaccine. This difficulty is also caused by vaccine patents owned by large pharmaceutical companies.

In October 2020, South Africa and India proposed through the WTO forum that IPR on vaccines and medicines and treatments related to COVID-19 be set aside for at least three years. This will allow more countries to produce vaccines to increase global supply. In addition, the level of public investment in vaccines is one reason for technology sharing. The Government itself has affirmed its commitment from the beginning to continue to promote equal access to vaccines for all countries. In addition, Indonesia also supports the abolition of COVID-19 vaccine patents in order to encourage world production capacity to increase vaccine supply. This proposal received opposition from developed countries as vaccine producers such as the European Union, UK, Germany, and France. The United States itself initially refused to ignore patent rights, but later changed its position to also agree on the option to temporarily waive IP protection for COVID-19 vaccines.

Proponents of the waiver or abolition of patents argue that this effort will lead to a significant increase in the production of a COVID-19 vaccine during the pandemic and could save many lives. But on the other hand, with the application of a patent waiver, manufacturers will be free to replicate vaccines, tests, and diagnostics for the corona virus without fear of violating the patents of pharmaceutical companies. Until the end of 2021, the supply of COVID-19 vaccines is still very limited, with many poor countries, especially in Africa, barely having access to vaccines. Meanwhile, proponents of COVID-19 vaccine patents are of the view that long-term neglect of patent rights will result in the reluctance of pharmaceutical companies to respond to global health threats appropriately and quickly in the future. In addition, the supporting element for the lack of vaccine supply is not because of access or patents or price, but because of the unavailability of raw materials, lack of human resource capacity and production materials.

**CONCLUSION**

Based on the results of the discussion above, it can be said that the policies taken by...
the government must be fair and wise, so in the public interest, the option to temporarily waive patent rights can be an option that can be explored together. Thus, all countries in the world have time to really fight and control the spread of COVID-19 and carry out economic recovery due to the pandemic. After the agreed period ends, COVID-19 vaccine inventors can enjoy their patent rights so that they do not decide the hopes and desires of the inventors to continue to conduct research and create other inventions in the future.

REFERENCES


Huang, Chaolin et.al. (2020). Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China.


Perlman, Stanley. (2020). Another decade, another coronavirus


