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Implementation the Tripss Safeguards on Develop Country in Dealing with the H HIV/AID Epidemic

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Abstract

The regulation of patent rights in TRIPSs is considered to be the cause of expensive drug prices due to its nature which gives exclusive rights to inventors or patent license holders to manufacture, use, offer and sell both products and processes. Nonetheless, TRIPSs actually regulates several models of flexibility over patents to protect the interests of developing countries. The provisions of the flexibility model in general actually aim to provide protection for public health in developing countries and can be used in the case of medicine. Indonesia as a TRIPSS participating country has the opportunity to take advantage of the flexibility model in drug-related patents. The author uses doctoral legal research or literature research with the issues discussed are how to implement the TRIPSs Safeguards in developing countries in overcoming the HIV/AIDS epidemic and how the TRIPSs provisions make use of cheap drugs in overcoming the HIV/AIDS epidemic in Indonesia. The result of the research is that the implementation of protective articles (The TRIPSs Safeguards) often leads to legal disputes among WTO members and issues of regulations in order to gain access to cheap drugs to overcome the HIV/AIDS epidemic.

Keywords: *Regulating Patents; The TRIPSs Safeguards; And HIV/AIDS Epidemic*

Introduction

Developing and poor countries still debate the protection of drug patents approved by WTO countries for WTO's agenda. After being used in many countries for about 16 years, drug patent protection causes problems in many developing and poor countries. As a result of numerous studies, some experts agree that drug patents impact prices and availability of generic drugs.

According to guidelines in the 2016 rule of patent number 13, it is the exclusive rights given to (discoverer) his invention in technology over a period of time. One heavily registered invasion in order to obtain a patent is a drug. Drug patents mean patents to drug brands manufactured by certain

pharmaceutical companies in accordance with legislation. Drug patents can only be registered by a patent clerk. Drug patent protection filing aims to authenticate medicines and prevent counterfeiters or counterfeits.

Because of drug patents, only inventors have the authority to practice their inventions or to authorize other people or businesses to perform them-in this example, pharmaceutical production. Despite the fact that they have maintained their patent, the drug patents only last for a certain period of time. By the rule of law, the patent law is 20 years old. After more than 20 years, the protection of a drug patent expired and could not be extended. If the drug patent expires, the omedicine in general already belongs to the public. Normally other unpatent pharmaceutical companies can submit to the production of the first generic drug from the drug patents that are running out.

Treaties TRIPSs, a reliable source of patent protection for medicine, now returns to the attention of the international community on the effects of that effect. Each country is allowed to take premature and significant action, according to chapter 8, to solve the problem of public health because of the protection of intellectual property (HKI). Many developing countries are requisitions of the developed battle council on WTO on TRIPSs, although prips allow for the use of this chapter and other provisions. Provisions that provide protection.

There is still a gap between the TRIPSs terms of the treaty and its implementation, evidence that there is disagreement between the United States and Brazil governments over the application of compulsory licenses. Legal dispute requires DSB, BTO involvement. A similar example further supports the findings that both developed and developing countries have different interpretations of how the TRIPSs antibiotics should be implemented. One example is the dispute between the South African government and multinational pharmaceutical firms on imported and compulsory licenses. Thriving and needy.

TRIPSs have harmed the preservation of public health. Drugs are expensive because the industrialized world produces most drugs. Studies indicate that drug patents raised the cost of drugs by 52% and caused social welfare costs of us $33 million, according to a study published by watal in 1996 (Utomo, 2010: 24; Watal, 1996:19–20).

Chapter 8 of the TRIPSs treaty gives WTO members the opportunity to enact important public health measures, but this has not been able to help poor countries such as African groups obtain cheap medicine. During the meeting in doha, Qatar (9-14 November 2001), WTO members approved the doha declaration) and reaffirmed the relationship between TRIPSs and public health.

This occurred as a result of a discussion surrounding African group proposals made in early 2001, followed by a request from the TRIPSs council to establish a link between the TRIPSs treaty and public health. If these countries can implement protective measures regularly (such as parallel imports and compulsory licenses), the price of drugs can go down. However, efforts to fit this safety frame into the national legal framework of developing and underdeveloped countries sometimes result in legal action from wealthy countries.

Because of the creation of drug patent protection, the doha declaration aims to address public health problems in both developing and underdeveloped countries. Article 4 of the doha declaration, for example, offers good justification to implement protection to preserve public health and increase access to the drugs needed. Furthermore, the doha declaration helps developing and retarded countries understand the TRIPSs protection requirement, which includes parallel imports and compulsory licenses. Paragraph 6-the use of the doha declaration in developing and backward countries with insufficient resources to produce medicines is a major problem.

The application of necessary licenses in the WTO countries is strictly for local markets, which is a serious problem according to chapter 31 (f) the TRIPSs treaty. It is forbidden to import or export pharmaceutical drugs made according to the proper permits. As a result, the required use of licenses is difficult for countries with low abilities or countries that cannot make any drug. This prohibition contradicts article 31 of TRIPSs, which makes it possible to use the necessary licenses to minimize the weakness of patent protection. (Utomo, 2010: 30).

For example, developing and retarded countries, which happen to be constantly buying products with the right to do so, must change their rules, their legal structure, and their system of enforcement to conform to TRIPSs 'values. The negative effects that developed during the adjustment phase of the TRIPSs deal, such as rising drug prices, were another consequence that had to be accepted. It is believed that this undesirable effect can be reduced by administering these protective items.

The use of self-protection in developing and poor countries seems to increase as the number of poor people worldwide is infected with such deadly infectious diseases as HIV/AIDS. A state-wide example of caring about the need for protective goods and has implemented these measures to address local public-health problems including Brazil, South Africa, and India. Southeast Asian countries have also taken precautions against the HIV/AIDS pandemic by passing legislation that permits generic versions of some drugs covered by patents, either through mandatory licenses or through government use.

The infection of human immunodeficiency virus (HIV) is a spectrum of diseases affecting immune cells, ranging from initial infection to advanced stage, with or without acute symptoms. The final stage of HIV infection, known as AIDS acquired, is defined as a group of symptoms or diseases caused by a decline in HIV infection (Fauci et al., 2009).

It remains to be seen how many people in developing and underdeveloped countries will have access to HIV/AIDS treatment in 2022 after the doha declaration because, according to chapter 31(f) TRIPSs, "such use will be permitted primarily for the provision of members' domestic markets that allow such use" and because it cannot make generic HIV/AIDS drugs, such as antiretroviral (arvs) and antifungal drugs, are to be exported. Countries that need HIV/AIDS treatment should have the ability to produce it independently.

Hence, with the above description, the author draws the heading " Implementation The Tripss Safeguards On *Develop Country* In Dealing With The H HIV/AID Epidemic."

Formulation of the Problem

1) How is the TRIPSs implementation of the strait country dealing with the HIV/AIDS epidemic?
2) How does TRIPSs use cheap drugs in dealing with the HIV/AIDS epidemic in Indonesia?

Research Methods

The word "research" comes from the word "re, "which means return, and "search", which means search. Research is the process of finding once again. It is a consistent, systematic, thorough scientific activity associated with analysis and construction. Consistent means not contradictory within a particular framework, systematic means by a system, and means methodology by a particular approach or method.[1]

[1] Soerjono Soekanto, *Pengantar Penelitian Hukum*, (Jakarta: Universitas Indonesia, 2010), hlm. 42.

Research is the process of information gathering through data collecting and analytical tasks completed transparently, deeply, organizationally, and accountable.[2] Research, according to soerjono soekanto, is a scientific activity aimed at extracting one or more specific legal phenomena through analytical processes. It is based on methodology, systemic, and particular ideas.[3] It may thus be concluded that research is a systematic process of processing, collecting, and data analysis that involves a set of techniques.

A method must be used in research to be more precise, purposeful, and methodical and that the results can be explained scientifically without arousing new doubts about the main issues that have been established. The study process has a wide range of objectives, including instructions on how to investigate, evaluate, and understand problems faced and improve the ability of researchers to do proper and comprehensive research.[4]

The writers of this magazine use libraries or PhD law studies when compiling them. Called the study of doctrinal law because it focuses solely on moral principles, social norms, and written laws. As a result, the study is closely linked to libraries because it requires secondary data from them. It is the product of the normatif research, which focuses on literature analysis using various secondary data sources, including legislative documents, various legal theories, and academic scientific study findings. Information is collected, qualitative, and then presented in a descriptive way.

Court judges gave full consideration to the rights of making matters a matter by keeping an eye on the potential benefits and benefits of the accused (judge made law). The normative-law concept is a norm that is synonymous with the justice values that must be realized (ius constituendum), as it is evident that positive laws have been carefully formulated (ius constitutum) to ensure certainty.

Discussion

1) The TRIPSs Implementation on the Globalization of the HIV/AIDS Epidemic

a) The South African Government

The South African government passed the amendment to the control of drugs and related substances act, sometimes known as the drug law, three (three) years after the TRIPSs treaty was made. According to article 15 c, the health minister has the authority to restrict the production of certain drugs by organizations other than patent holders (compulsory licenses).

A key purpose of the law is to make it easier to import high-quality, affordable HIV/AIDS drugs from other countries and to encourage the production of this drug in South Africa. The South African government set up CIPLA-medpro, a joint venture made up of cipla companies and local businesses, to achieve this goal. The aim of this company is to produce medicines related to South Africa, including zidovudine, stavudine, and lamivudine.[5]

A large number of pharmaceutical companies disagree with this approach, claiming that it contradicts article 27 of the TRIPSs treaty. The growing number of HIV/AIDS sufferers, reaching the highest documented figures anywhere in the world, led the South African government to believe that this

[2] Hilman Hadikusumo, *Metode Pembuatan Kertas Kerja/Skripsi Ilmu Hukum,* (Bandung: Mandar Maju, 1995), hlm. 6.
[3] Soerjono Soekanto, *Pengantar Penelitian Hukum,* (Jakarta: UI Press, 1986), hlm. 15.
[4] *Op.cit.*, Suteki, hlm. 149.
[5] Andy Gray et al, *Policy Change in a Context of Transition: Drug Policy in South Africa 1989-1999*. Centre for Health Policy, School of Public Health University of Witwatersrand, hal. 18, http://www.wits.ac.za/chp/m76.pdf (2002); *see* also Stephen Barnes, *Pharmaceutical Patents and TRIPS; A Comparison of India and South Africa,* 91 KY. L. J. 911, 10 (2002-2003).

policy does not conflict with the TRIPSs agreement.[6] According to experts, "more than three million people in South Africa will die of AIDS." Around 2005.[7] Despite the fact that there are many pharmaceutical drugs on the market for treating HIV/AIDS, the majority of south africans cannot afford them because of their high prices. The price.

The fact that South African governments have never viewed HIV/AIDS as a national emergency or asked for a license to produce generic HIV/AIDS drugs is interesting.[8] According to many observers, trade sanctions from developed countries are warned against the South African government, particularly the United States and other western countries.[9]

The 1997 South African drug law was criticized by the U.S. government in 1998 for insufficient protection of pharmaceutical goods. In response to this criticism, the U.S. government added South Africa to its list of protections along with other countries it believed were not offering adequate HKI protection. South Africa was finally released from the U.S. government's watch list in 2001 for combating the spread of AIDS that has claimed many lives there.[10]

b) The Brazilian Government

To encourage the development of generic HIV/AIDS drugs, the Brazilian government introduced a compulsory license in 1996. The necessary licensing policies are implemented in view of the fact that there is an increase in the number of AIDS cases in Brazil, but most brazilians are not able to do so. Buying new HIV/AIDS drugs because they are high. Governments have commissioned that all pharmaceutical producers produce eight types of generic HIV/AIDS drugs as part of the license, and AIDS patients are then given them free of charge.[11]

Governments have also enforced strict regulations on licenses requiring local labor, in which pharmaceutical companies have proved that they have been using their patents in Brazil for 3 (3) years since their intellectual rights were granted.[12] There is only one exception to local work requirements, that if a patent holder can point out that the production of drugs covered in the patent has no economic benefit to the patent holder. If this is established, the rules relating to the required license will not be applied.[13]

The Brazilian government has set out a number of other actions besides the requirements for legalized license, such as producing HIV/AIDS drugs without the protection of Brazil's patent laws. The Brazilian government tried to bargain with the patent holders first for the medicines covered by the patents. The government must approve before patented drugs can be produced; Otherwise, compulsory licenses will be required. Since the permit is granted under the circumstances or conditions of high public health, the government of Brazil believes that the various regulations are in agreement with the TRIPSs.[14]

However, the Brazilian approach was strongly opposed by the U.S. government, which regarded this as a patent violation. To verify that article 68 of Brazil's patent laws, which established the basis for necessary license enforcement, the United States government filed a formal lawsuit against the Brazilian

[6] Richard Gester, *People Before Patents-The Success Story of the Indian Pharmaceutical Industry*, http://www.gesterconsulting.ch/docs/India%20_Pharma_Success_Story.pdf, hlm.6.
[7] Naomi A. Bass, *supra* note 51, hlm. 11.
[8] *Ibid.* Harga obat untuk penyakit tersebut sangat mahal bagi kebanyakan penduduk Afrika Selatan, yaitu berkisar antara $12,000-$15,000 per orang per tahun
[9] *Ibid.*
[10] *Ibid.*
[11] *Ibid*. hlm. 11-12.
[12] Anthony P. Valach, Jr. TRIPs: *Protecting the Rights of Paten Holders and Addressing Public Health Issues in Developing Countries*, 4 Chi-Kent J. Intell. Prop 156, 6 (2005)
[13] *Ibid*
[14] *Ibid.*

government against the WTO dispute panel on January 8, 2001. The United States and Brazil reached an agreement on June 23, 2001, in which the United States would cease its legal action against Brazil because the program has reduced the number of aids-related deaths there. The Brazilian government also agreed to inform the U.S. government about and evaluate the mandatory licensing clauses found in Brazil's patent laws at the same time.[15]

Therefore, the solution to the 2005 amendment protocol also refers to the TRIPSs 'changing protocol, adopted by the WTO general council on December 6, 2005. With the help of these protocols, the TRIPSs treaty will now have the added flexibility to provide some of the necessary permits for the manufacture and export of drugs to countries with inadequate or totally inadequate pharmaceutical production capabilities.

But the aim of general flexibility is to maintain public health in the backward countries. These are some laws that can be used to give low-income people access to affordable prescription purchases. One factor that affects public health is ease access to affordable drugs. Parallel import, license requirements, and patent enforcement by government are examples of the flexibility trips on drug patents. Lower drug prices were made possible by three flexibility models.

2) **TRIPSs Provisions Make Good Use of Cheap Drugs in Dealing with the HIV/AIDS Epidemic in Indonesia**

Illustration of a public health problem in Indonesia. The two countries responsible have antiretroviral treatment licenses (ARV) are India and Thailand. Antiretroviral drugs derived from India and mushroom remedies from Thailand were still imported by India in 2002. By comparison with a patent drug that cost $3,900,000,000.00, three types of antiretroviral drugs purchased from India at a cost of $650,000,000. within a month. Similar to an anti-fungal drug, a fluconazole price of 150 mg proprietary is $75,000,000.00 an item, compared to $3,000,000.00 for a fluconazole of 200 mg of Thai. Patients with HIV can purchase drugs according to the budget of generic drugs (compasses, November 27, 2002).

The above-mentioned circumstances are alarmingly high, and the wto has not reacted immediately to all the consequences that TRIPSs 'protection of patent drugs would have. Medicines are expensive because patent holders have a grip on them, but when it comes to public health, this scenario cannot be permitted. Practical answers that can improve public health in developing and underdeveloped countries must be found immediately.

The TRIPSs council agrees with the presence of paragraph 6 of the 2003 doha declaration adopted by the general council in response to health problems faced by both developing and underdeveloped countries (Utomo, 2010:30– 31).

Some provisions under article 31 of the TRIPSs deal have been abolished, particularly chapter 31(f) and (h), according to the 2003 decision of the 2003 TRIPSs general board (application of paragraph 6 of the doha declaration on the TRIPSs treaty and the August 30, 2003 public health general board). By permitting the export of certain drugs to importing countries with suitable licenses, this rule expands the scope of compulsory licenses, currently restricted to the domestic market of members under section 31(f) TRIPSs.

The emergency situation and non-commercial applications are two potential justifications to implement clause 6. Export and import countries are the two parties who must meet the requirements for a paragraph 6 system. The following criteria must be met in order for a country to export goods (Utomo, 2010:31–34).

[15] *Ibid.*

a) The export countries make sure that the amount of drugs made according to the needs of the importing countries and sent only to the country really does.
b) According to the guidelines in paragraph 6 of the system, the export countries label label drug products under a license. A brand must be easily identified through packaging, labeling, color, and/or distinctive shapes. Pricing should not be affected by the marking. Explain details about the number of items, locations, and unique qualities that are sent on the web site before giving a price.

The following criteria must be met if a country can import:

1) Inform the TRIPSs council by the name and number of the required products.
2) Informing the TRIPSs council on the difficulties of the country as developing countries do not have or do not have the adequate ability to produce medicines.
3) The importing state has the responsibility of ensuring that the use of the necessary licenses is contained under chapter 31 of the TRIPSs covenant and the rule of paragraph 6 of the system if the needed medicinal products are covered by patents in its country.

In an effort to combat the HIV/AIDS epidemic, the 2004 government of Indonesia's 83rd President's decision to implement a government patent on antiretroviral drugs. 2004. This decision calls for access to affordable drugs.

WTO members decided in 2005 to revise the TRIPSs treaty to support the 2003 decision. Because of decisions made by wto members, two new rules have been introduced into the TRIPSs treaty:

a) article 31bis is added to the original TRIPSs treaty after chapter 31. This page includes a general guide on how to apply mandatory licenses to import and export countries.
b) chapter 73 of the TRIPSs covenant was previously changed by adding an appendix (Utomo, 2010: 34).

The amendment's success suggests that the TRIPSs 'rules are flexible and are still flexible. TRIPSs, an international law, is a rule set out within the framework of the competition of interest of some superpowers. In international economic terms, economic strategies serve as political tactics. National interests must be considered when understanding the TRIPSs, which Indonesia has ratified as a member of the WTO.

Ratification rule on the patents of infectious diseases and HIV/AIDS drugs in Indonesia:

1) Act 23 in 2013 on drug management,
2) Government regulation number 27 in 2004 on patent enforcement ordinances by government,
3) President 83's 2004 decision on government patent implementation of anti-retroviral drugs,
4) 2013 health minister number 21's rule on hiv and aids management,
5) Health minister number 51 of 2013's rule on mother-to-child prevention guides for hiv transmission
6) 82-2014 ministry of health ministry regulation on infectious - weed management,
7) The 67-year 2016 ministry of health regulation on the standard of health care in the public center
8) Indonesia's health ministry's 2022 year rule on the management of human immunodeficiency virus, acquired immuno - deficiency syndrome, and sexually transmitted infections,
9) The 76 year 2012 presidential rule on government patent implementation of antiviral and antiretroviral drugs,
10) The decision of the ministry of health of the republic of indonesia no.01.07/menkes/90/2019 on the national guidelines of hiv ordinance medicine service

11) Indonesia's ministry of health, no.109/menkes/sk/iii/2013, regarding the appointment of up to.
12) Rule no.02/per/menko/kesra/i/2007 minister of public welfare coordinator on the national policy of hiv and aids treatment through a reduction in the negative effects of drug use, psychotropic, and addictive drugs,
13) And so on.

TRIPSs should not harm the interests of a country when implemented. The international lobby of developing and poor countries must speak and be well-informed with developed countries to create a balance between global demands and national interests. Of course, Indonesia, while at wto member meetings, must be proactive and capable of maximizing negotiation and diplomacy. To fulfill his duty to defend national interests.

To fight the HIV/AIDS epidemic at a low cost, the Indonesian government has imposed the TRIPSs. As a result, the 2004 decision of the President, no. 83, was issued on the government's patent implementation of antiretroviral drugs, which was subsequently altered with the President's decision of no. 6, 2007. To combat the HIV/AIDS epidemic, antiretroviral drugs held by foreign pharmaceutical companies are manufactured in government-designated pharmaceutical manufacturers. The government replaced the 2012 press with a 2012 presidential decree of 76 on implementing the government's patent on antiviral and antiretroviral drugs (the final patent will be issued in 2018 and 2024).

Conclusion

WTO member countries should consider various factors in implementing the TRIPSs protection provisions, including the differences in economic development between them and the previous legislative skill and policy making in public health. The inclusion of the protected articles (the TRIPSs surveys) is certainly a crucial and can be used asa link to balance the interests of the patent owners and of the general public as user of the hki product. But, in reality, the application of TRIPSs techniques often leads to legal conflict between wto members.

TRIPSS 'patent protection laws once made it possible for developing and underdeveloped countries to access expensive drugs. As a result, paragraph 6 of the declaration of prayer was issued by the TRIPSS general council in 2003, and in 2005 it changed chapter 31 after chapters 31 and chapter 73 with the appendix to addressing the interests of countries struggling to produce their own medicine. On provisions trips has been used by the Indonesian government to gain access to cheap drugs for the fight against the HIV/AIDS epidemic.

The requirement for wealthy countries, especially in developing and poor countries, is to interpret the function of international treaties such as the TRIPSS articles. If this is achieved, legal problems that often stain relations between two or more national groups can be reduced, while maximizing the function of self-protection in countries that need it.

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