

## Legal Discourse of United States Pharmaceutical Industry Mandatory License and Trips Agreement Post Doha Declaration

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### Abstract

The public health crisis related to HIV/AIDS, Tuberculosis and Malaria, was the starting point for the World Trade Organization (WTO) Ministerial Conference in 2001 which adopted the Doha Declaration on the TRIPS (Trade-Related Aspects of Intellectual Property Rights) and Public Health Agreements. The pharmaceutical industry as one of the knowledge driven sectors especially pharmaceutical research is very expensive and unpredictable. Making the patent system as a legal protection tool to facilitate innovation related to pharmaceutical products. The similarities between United States patent law and the TRIPS agreement also demonstrate United States's influence in setting intellectual property standards globally. This research is a juridical-normative research using a statutory approach. The data collection technique was carried out by means of a literature study. Data analysis technique: qualitative normative analysis. The results showed that the United States' dissatisfaction with the level of intellectual property protection provided by the TRIPS agreement encouraged the development of the provisions of the TRIPS-Plus agreement in the United States Free Trade Area (FTA). The terms of the TRIPS-Plus agreement appear to be designed to negate the effective use of mandatory licensing by blocking the marketing of third-party drugs during the term of the patent. However, the TRIPS agreement retains some flexibility for World Trade Organization members, such as the data exclusivity and mandatory licensing outlined in the Doha Declaration.

**Keywords:** Legal Discourse; Compulsory License; Pharmaceutical Industry; TRIPS Agreement.

#### History:

Received: January 11<sup>th</sup> 2022

Accepted: January 17<sup>th</sup> 2022

Published: February 1<sup>st</sup> 2022

**Publisher:** Universitas PGRI Madiun

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### Introduction

Public health crises particularly in the areas of HIV/AIDS, Tuberculosis and Malaria especially in low- and middle-income countries (Sandra Bartelt, 2003) do not have access to effective medicines, often because they are not affordable (Hoen, 2018). As is well known, drugs supported for the treatment or prevention of disease, prevention of pregnancy, rehabilitation, correction, or alteration of physiological functions in humans are subject to comprehensive public control at all stages of their market cycle (Vipin, 2012). The World Trade Organization (WTO) Ministerial Conference in 2001 adopted the Doha Declaration on the TRIPS (Trade-Related Aspects of Intellectual Property Rights) and Public Health Agreements (Barizah, 2017). The declaration recognizes the implications of intellectual property rights for new drug development and drug prices (Kolawole, 2012). The Declaration outlines the steps known as TRIPS flexibility that WTO Members can take to ensure access to medicines for all (Permanand, 2006). The WTO has a Ministerial Conference and a General Council, which, among other things, function as the DSB (Putri, 2021).

The TRIPS agreement covers seven forms of intellectual property namely patents, copyrights, trademarks, industrial designs, geographical indications, integrated circuit layout designs, and protection of confidential information or trade secrets (Nazura, 2016). Pharmaceutical patents can be classified in the following categories (UNDP, 2015):

- a. Medicinal compound patents;
- b. Formulation/composition patent;
- c. Synergistic combination patent;
- d. Technology Patents;
- e. Polymorph Patent;
- f. Biotechnology patents;
- g. Processing patents.

The patent system as the most common and effective legal protection instrument for innovative facilities related to pharmaceutical products is still controversial. The pharmaceutical industry is one of the most intense knowledge driven sectors especially pharmaceutical research is very expensive and unpredictable (Vitaliy & Pashkov, 2016). The United States and several other members have put pressure on developing members to accelerate the application of patent protection to pharmaceutical products. In its filing with the TRIPS Council on access to medicines, the United States promoted the adoption of strong patent protections and prohibited the extension of the transition schedule. The United States filing is based on the assessment of American pharmaceutical companies that have spent more than 50,000,000,000.00- (fifty billion) dollars in Research and Development (R&D) each year to bring new drugs to market. If generic pharmaceutical companies in foreign markets are able to evade American patent protection by continuing to import these drugs, then there is little incentive for American pharmaceutical companies to develop drugs that will help these developing countries.

Regardless of whether mandatory licensing laws can produce positive results, they can not be enforced in the United States unless they can be passed by the constitution. Article I section 8 paragraph 8 of the Constitution is the primary source of Congress authority to legislate on intellectual property. The clause, commonly known as the "Patent and Copyright Clause" provides that Congress has the power to promote the useful Advancement of Science and the Arts by granting Authors and Inventors Exclusive Rights for a limited time to their respective Writings and Inventions.

Intellectual Property Rights are a form of creativity of a person resulting from the thought and intention of humans, not all humans can create copyrighted works produced by their thinking power to create a work of creativity must have a very high imagination (Sigratama, 2021). The purpose of the TRIPS agreement is to promote industry especially in developing countries and protect intellectual property, theoretically reducing trade barriers, which in turn will increase the growth and development of developing countries. Therefore, the World Trade Organization strives to advance the industry by creating international patent protection. While the ultimate goal of the TRIPS agreement is to advance public health. In conjunction with the first goal which seeks to protect Research and Development (R&D), this goal tries to strike a delicate balance between the short-term goal of providing access to existing medicines and the long-term goal of developing new medicines through incentives for research and future development.

In addition, maximum flexibility in the application of domestic laws and regulations to enable "developing countries" to create a sound and viable technology base. Meanwhile the World Trade Organization wants to allow mandatory licensing to combat the public health crisis. The World Trade Organization simultaneously wants to promote self-sufficiency in developing countries through the manufacture of their own medicines. This

dual goal is self-reliance and health crisis management which clearly contradicts the current way of using compulsory licensing (Lacayo, 2002). The United States initiated a number of unfair trade cases against developing countries for "inadequate" intellectual property protection, extracting concessions in some cases.

Under The Doha Declaration on The TRIPS Agreement and Public Health, World Trade Organization's members are committed to implementing and interpreting the TRIPS agreement to allow for its full flexibility and to promote access to medicines for all (Ellen, 2002). The Declaration provides unequivocal acknowledgment of the right of a member to grant a compulsory license on a basis determined by the member. Provisions relating to patents and regulatory approvals related to drugs in the Free Trade Area (FTA) that the United States recently agreed such as the Dominican Republic–Central America Free Trade Agreement (CAFTA) and The US-Morocco Free Trade Agreement (USMFTA).

The agreements are likely intended to limit the flexibility inherent in the TRIPS agreement and the Doha Declaration on the TRIPS Agreement and Public Health. It appears to have been deliberately designed to negate the effective use of mandatory licensing by blocking the marketing of third-party drugs during the term of the patent (Frederick, 2003). Of course the agreements entered into by the United States and the members of the Free Trade Area will violate the principles and content of Article 31 of the TRIPS agreement and paragraphs 6 and 7 of the Doha Declaration on the TRIPS Agreement and Public Health, which should be interpreted and implemented with ways that support the rights of World Trade Organization members to protect public health, in particular to promote access to medicines for all.

## **Materials and Methods**

This research is a juridical-normative research using a statutory approach. This paper is entirely based on a literature study of various legal materials. All legal materials are analyzed by conceptual justice theory from John Rawls. The data collection technique used is literature study and the data analysis technique used is qualitative normative analysis.

## **Results and Discussion**

Major advances in medical technology have important role of social health determinants for the etiology, prevalence and prognosis of disease. This changes the content of the concept of the right to health from a demand for health services to a claim to have access to all determinants of social health (Daniels, 2001). Thus, the equitable allocation of scarce health resources and the determinants of social health becomes a matter of ethical theory.

John Rawls developed a theory of justice that the principle of justice must be determined by individuals in a hypothetical initial position (Ekmekci et al, 2015). In the initial position, individuals agree on the principle of justice and Rawls argues that the institutions of society must be formed according to these principles in order to achieve a justice social system. Although Rawls does not justify the right to health in his theory, efforts to expand the theory to include the right to health are growing rapidly.

The patent statutes of United States' trading partners include general provisions that allow the granting of a mandatory license under certain conditions. These circumstances include public health needs, insufficient supply of patented inventions, failure to practice patented inventions in jurisdictions and other reasons of public interest. Reportedly, a number of jurisdictions have enforced this provision since the emergence of the TRIPS agreement, a number of important incidents relating to mandatory licensing of patented inventions, with Brazil, India, South Africa, and Thailand (Vera, 2008).

### **a. Brazil**

United States initiated process before the World Trade Organization alleging that Brazilian law violated the TRIPS agreement. In particular, United States alleges that Brazilian law violates the TRIPS agreement requirement that patents be enjoyed without discrimination as to whether the patent is imported or locally produced. Brazil and United States finally agreed on a mutually satisfactory situation in which Brazil agreed to hold talks with United States government before granting mandatory licenses to patents owned by United States companies (Jarrod, 2013). Under Laws year 1997, Brazil issued a mandatory license in 2007 for the AIDS drug efavirenz, which is sold by Merck & Co. under the Stocrin trademark (Mariana, 2013). Merck reportedly lowered the selling price of efavirenz to the satisfaction of the Brazilian authorities after the issuance of the mandatory license, so this action is debatable. In addition, the Brazilian government is reported to have used the threat of issuing mandatory licenses to receive discounts on AIDS therapy (Bakhsh, 2012).

b. India

On March 9<sup>th</sup> 2012, the Patent Supervisor issued India's first compulsory license. The mandatory license relates to the chemotherapy drug sorafenib, which is sold by Bayer & Co. under the Nexavar trademark. According to Controller, the purchaser failed to provide enough Nexavar to public demand, not selling Nexavar at an affordable price, and does not manufacture Nexavar in India. As a result, Controller granted a license to Natco Pharma Ltd., an Indian generics company, to manufacture a generic version of Nexavar. (Naval & Dino, 2012). Based on the Supervisory decision, Natco is required to pay a royalty of 6% of the net sales of the drug to Bayer. The Intellectual Property Appeals Council of India supported the decision of the Controller on 4 March 2013, despite increasing the royalties owed to Bayer from 6% to 7%. After granting the mandatory license of Nexavar, Indian authorities are reportedly considering mandatory licensing of prescription drugs used to treat breast cancer such as Genetech Herceptin, IXEMPRA and SPRYCEL for leukemia drugs from the Bristol Myers Squibb trademark (Staton, 2021).

c. South Africa

In 1997, South African legislature established a law allowing among other conduct, mandatory licensing of patented drugs. South African Association of Pharmaceutical Manufacturers and a number of pharmaceutical companies subsequently initiated litigation, alleging that the law violated the TRIPS Agreement and South Africa's own patent law. South Africa agreed to reform pursuant to the TRIPS Agreement and consulted with the pharmaceutical industry on the proposed amendments, while the pharmaceutical industry agreed to drop the lawsuit (Naomi, 2002). In the United States, the incident reportedly prompted the issuance of an Executive Order by President Clinton on May 10<sup>th</sup> 2000. The order prohibits the United States from taking action pursuant to Section 301 sub-section (b) of the Trade Act of 1974 with respect to statute or policies in beneficiary sub-Saharan African countries that promote access to HIV/AIDS for pharmaceutical or medical technology and that provide adequate and effective intellectual property protection in accordance with the TRIPS agreement (George, 2011).

d. Thailand

Thailand issued seven mandatory patent licenses from 2006 to 2008. The mandatory licenses relate to patents claiming:

- 1) AIDS drug efavirenz (sold by Merck & Co. under the trademark Stocrin) (Suntrajarn, 2021);

- 2) The AIDS drug combination of lopinavir and ritonavir (sold by Abbott under the brand name Kaletra);
- 3) the antiplatelet drug clopidogrel (sold by Bristol Myers under the brand name Plavix);
- 4) Breast cancer drug Letrozole (sold by Novartis AG under the trademark Femara);
- 5) Docetaxel, a breast and lung cancer drug (sold by Sanofi-Aventis under the trademark Taxotere);
- 6) The lung, pancreatic, and ovarian cancer drug erlotinib (sold by Roche under the trademark Tarceva; and
- 7) The cancer drug Imatinib (sold by Novartis AG as Gleevec).

Thailand's mandatory licensing has been controversial because of its relatively large number, Thailand's status as a middle-income country, and concerns that the Thailand's government is not complying with the TRIPS Agreement. In addition, five of the mandatory licenses relate to drugs to treat cancer and heart disease, chronic and non-communicable diseases that are common in developed countries. However, public health advocates laud the Thai government's willingness to meet the needs of its citizens.

The international debate over drug marketing approval data is mainly related to regulations that apply in World Trade Organization members regarding the efficacy, safety, and quality of drugs (Sykes, 2002). Similarly, regardless of the investment of time and funds required for the discovery of new drugs, where patents are the usual prize. Drug developers must undertake the painstaking and time-consuming task of obtaining marketing approval from the government agency responsible for protecting public health. In United States, these agencies include the Food and Drug Administration (FDA) and The Centers for Disease Control and Prevention (CDC) (Ellen, 2002).

Food and Drug Administration requires pharmaceutical manufacturers to document evidence of safety and efficacy. Evidence shows require significant pre-market testing costs when combined with research and development costs, they mandate large capital investments to manufacture innovative drugs. To protect this investment and prevent unsafe drugs from entering the market, the Food and Drug Administration maintains an exclusivity market protection system that protects branded drugs from generic competition for a period of time, usually three or five years (Adam, 2009).

It is important to emphasize the importance of patent protection in continuous pharmaceutical innovation and new drug creation. Developing new drugs is an expensive and very risky business because not all new drugs are guaranteed to be profitable. In fact, research has identified that most drugs fail to recoup their research and development costs and that small amounts of so-called "blockbuster" drugs are needed to make up for the losses on most low-paying products. For this reason, patent protection is essential to cover the costs incurred in developing new drugs.

One of the main barriers to the development of new drugs in the United States is regulation within the Food and Drug Administration. Although regulation is clearly needed to protect consumers, regulatory complexities within the Food and Drug Administration make the United States the most difficult country in the world to obtain market approval for new drugs (Stephen Gorove, 1980).

There are a large number of mechanisms, both in United States and worldwide, to regulate the research, manufacture, distribution, and postmarketing control of biopharmaceuticals. In the United States, the Code of Federal Regulations (CFR) governs this process. Section 355 of Title 21, the Code of Federal Regulations regulates food and medicine for three federal agencies:

- a. Chapter I, namely the US Food and Drug Administration;

- b. Chapter II, namely Drug Enforcement Administration; and
- c. Chapter III, namely the National Drug Control Policy Office.

The Food and Drug Administration's power to regulate drugs came about under The Food, Drug, and Cosmetic Act (FDCA) of 1938 which mandated that the Food and Drug Administration protect the American public by ensuring the purity, effectiveness, and safety of pharmaceuticals in the market. However, the Food and Drug Administration is not geared to facilitate the development of new drugs, regardless of their value to consumers. Consequently, a Food and Drug Administration mandate that directly contradicts the notion that pharmaceutical operations may be given special consideration when subject to Food and Drug Administration regulations requires such operations to strictly comply with all current regulations.

In United States, the experiments and testing required to secure regulatory authorization to market generic drugs can be carried out and applications for approval can be filed before the patent expires without a patent permit (Jeffery & Hans, 2014). These patent infringement exceptions are called the Roche-Bolar provisions (Bolar provisions). The Roche-Bolar provisions, named after the case of Roche Products, Inc. v. Bolar Pharmaceutical Co., is a court case in the United States relating to the manufacture of generic drugs. Bolar is a generic drug manufacturer. Roche is a branded pharmaceutical company that manufactures and sells Dalmane, the active ingredient of which is patent protected. Shortly after Roche v. Bolar decided, Congress passed a law allowing the use of patented products in experiments for the purpose of obtaining FDA approval of the Drug Price Competition and Patent Term Restoration Act, which is informally known as the Drug Price Competition and Patent Term Restoration Act. (Hatch-Waxman Act of 1984) which establishes a modern system for FDA approval of generic drugs (Kolawole, 2005).

It started when the regulatory authorities from Europe, Japan and United States as well as experts from the pharmaceutical industry had met to find ways to make the technical requirements for the regulation of new drug substances and products uniform to eliminate repetition and avoid duplicate activities with the aim of accelerating global development and availability of new drugs without loss of quality assurance, safety or efficacy. This serious and comprehensive effort is under the auspices of seven co-sponsors as the umbrella organization for the entire pharmaceutical industry (OECD, 2002), namely, the Commission of the European Communities and the European Federation of Pharmaceutical Industries Association (EFPIA), the Ministry of Health and Welfare (MHW) and the Japan Pharmaceutical Manufacturers Association (JPMA), the Food and Drug Administration (FDA), the Pharmaceuticals Manufacturers Association (PMA), and The International Federation of Pharmaceutical Manufacturers Association (IPFMA) (Worden, 1995).

The pharmaceutical industry, a significant source of healthcare worldwide has several characteristics that distinguish it from other healthcare industries (Joan, 2002). Advances in pharmaceutical research and development have resulted in the production of drugs that can routinely combat diseases that just a few years ago, were incurable or even fatal. Since 1970, the share of the average Gross Domestic Product (GDP) in pharmaceutical goods has increased in most Organization for Economic Cooperation and Development (OECD) countries by around 50%, which means that pharmaceutical spending has increased by an average of 1,5% more per year than Gross Domestic Product growth.

Despite the media attention paid to the “compulsory licensing” debate. In fact, patents and international patent protection obligations are not the main obstacle to adequate supply and distribution of drugs in developing countries (Susan, 2002). On the other hand, the adoption of international trade rules that can further enhance such access is hardly acceptable. However, economically developing countries have consistently pushed for interpretations of

the TRIPS agreement that would place a price on large pharmaceutical companies in boating monopolies for unpatented or patented drugs, through guaranteeing exclusive rights to clinical testing data required for marketing approval. Analysis and resolution of the debate on control of drug test data at the level of positive international law and international drug policy is urgently needed (Aaron, 2004).

Article 31 of the TRIPS agreement stipulates a mandatory license which gives the government broad discretion in issuing the license (Donald, 2011). The following requirements must be met to obtain a mandatory license (Pedro & Christoph, 2006):

- a. States should ensure that third parties requesting licenses seek to obtain authorization from the patent holder on a commercially reasonable basis;
- b. The scope and duration of a mandatory license shall be limited to the purpose for which the license is authorized;
- c. The compulsory license must be used predominantly for the domestic market supply of the member that permits such use and lastly;
- d. States should provide patent holders with adequate remuneration taking into account the economic value of the authorization. Article 31 can be revoked in cases of extreme urgency, national emergency, or public non-commercial use.

When governments issue mandatory licenses, the result is often a sharp drop in prices, similar to the emergence of other competitive forces such as generics. For this reason, many developing countries are debating the right to issue mandatory licenses for medicines that are usually very expensive for their citizens. However, during the negotiation of the TRIPS agreement most developed countries debated harsh restrictions on compulsory licenses to protect the domestic pharmaceutical industry. Thus, real tensions between developing and developed countries are increasing over the use of compulsory licenses.

Developing countries are frustrated by the lack of clarity around terms such as “adequate remuneration” and “national emergency” (Antony, 2008). Since many low-income countries lack production capacity, mandatory licensing under Article 31 does not provide a viable method of obtaining competitively priced medicines (Laura, 2010). At the same time, awareness of HIV/AIDS, malaria and tuberculosis is increasing as developing countries struggled to contain and treat infectious disease outbreaks, these concerns led to the signing of the Doha Declaration at the World Trade Organization Ministerial Conference in 2001.

Efforts to gain access to affordable medicines were further strengthened by the birth of the Doha Declaration on the TRIPS Agreement and Public Health at the Ministerial Conference in Doha in 2001. The existence of the Doha Declaration on the TRIPS Agreement and Public Health was a response to complaints from developing countries about its ineffectiveness in protection articles in the TRIPS agreement. As the TRIPS agreement stipulates flexibility in “compulsory licensing” which is a solution to the problem of access to medicines in developing countries. Compulsory licenses are basically unknown in the TRIPS agreement, but the basic principle is contained in Article 31 of the TRIPS agreement regarding the use of patents without the permission of the patent holder (Totok, 2002). Under the TRIPS agreement, each country has the right to issue permits for the implementation of mandatory licenses (Tomi, 2007).

Finally In 2005, the members of the World Trade Organization have reached an agreement to amend the TRIPS agreement regarding the decision of the World Trade Organization on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This decree creates a mechanism to allow members of the World Trade Organization to enforce temporary drug patents through the export of generic versions of patented drugs to countries with insufficient capacity or no industry in the pharmaceutical sector. The provisions of the Doha Declaration on the TRIPS Agreement and

Public Health contain seven paragraphs providing an interpretation of Articles 7 and 8 of the TRIPS agreement regarding the objectives and principles of the TRIPS agreement itself.

United States had to accept compromises during negotiations and remain dissatisfied with the level of protection afforded to pharmaceutical patents by the TRIPS treaty. This dissatisfaction prompted the development of the provisions of the TRIPS-Plus agreement in the United States bilateral Free Trade Area (FTA). Such provisions seem designed to prevent access to medicines for poor populations (Frederick & Jerome, 2007). The similarities between the United States patent law and the TRIPS agreement demonstrate the influence of the United States in setting global intellectual property standards (Mcgill, 2009). Despite the success of the United States in shaping global intellectual property. The TRIPS agreement retains some of the flexibility, namely data exclusivity and mandatory licensing, which the Doha Declaration affirms (Caroline, 2010). The United States' dissatisfaction with the level of intellectual property protection provided by the TRIPS Agreement led to the development of the provisions of the TRIPS-Plus agreement in US FTA's.

The TRIPS Agreement now denies fatigue. In this context, political agreements regarding the provision of patented medicines to World Trade Organization members suffering from public health emergencies would require price discrimination to be effective (Jeffery & Hans, 2014). While the amendments facilitated the issuance of compulsory licenses, the emerging reality is that the threat of mandatory licenses has helped persuade intellectual property holders to provide needed medicines at low prices. However, the United States strongly opposes the issuance of mandatory licenses for various reasons. The United States has banned the use of compulsory licensing for a variety of altruistic reasons, including the promotion of scientific research and industrial development in developing countries, the protection of ailing populations from inappropriate administration of strong drugs, and adherence to international treaties that enforce these policies. The most consistent complaint by the United States is that compulsory licenses violate international intellectual property laws defined in the TRIPS treaty.

After observing some of the symptoms of the debate regarding compulsory licensing regulations, there are several recommendations in dealing with the mandatory licensing law discourse in the United States pharmaceutical industry, such as regulatory solutions, extending patent life, and suspension. First is regulation, the US Food and Drug Administration (FDA) has the authority to pause or slow down, the rate at which new and evolving American medicines are traveling. This will continue until American pharmaceutical companies assist developing countries by providing generic drug patent information, manufacturing drugs, and/or distributing drugs. This arrangement would prevent American pharmaceutical companies from bringing new drugs to market until they comply with the mandatory licenses granted to them. Second is Patent Life Extension, in this solution the United States Patent Office will allow pharmaceutical companies willing to participate in mandatory licensing to extend the life of their patents by a few months or a year. This solution would be a more "pharmaceutical friendly" option for American pharmaceutical companies than the first proposed regulatory solution. The third is suspension, in which the World Trade Organization will establish an international committee that can investigate allegations of abuse. The Committee will have the power to suspend a country from the World Trade Organization if found guilty of a practice that is inconsistent with appropriate patent protection policies. This suspension will serve to deter countries from engaging in practices that have not necessarily been initiated due to a national emergency.



## **Conclusion**

Based on the description above, the conclusion of this paper regarding the ability of patent granting countries to issue compulsory licenses has shown that the rules stipulated under the TRIPS agreement are quite liberal. Political agreement reflects liberality enough as mandatory licenses are not limited to patents related to infectious diseases (HIV/AIDS, Tuberculosis and Malaria), but are also not limited to health emergencies. Overall, the TRIPS agreement provides contains flexibility that can be used by member countries to increase access to medicines through mandatory licensing mechanisms. United States discontent with the outcome of the deal during the negotiations has led to the development of the TRIPS-Plus agreement in the Free Trade Area (bilateral) that appears to be designed to block access to drugs. In the United States, mandatory licensing of patented inventions highlights the tension between the two competing aspirations of the patent system. On the one hand, encouraging a workforce that leads to innovation, and on the other hand placing the results of that work in front of the public. Patenting countries have different interests and different perceived values with respect to innovation, property rights, and public health and other social needs. This resulted in legal discussions regarding mandatory licensing of the pharmaceutical industry and conflicts between jurisdictions after the Doha Declaration mandated negotiations aimed at clarifying or improving discipline with procedures under the provisions of the World Trade Organization.

## **Acknowledgments**

The author expresses his gratitude to God the Almighty and to his family, so that this article can be completed properly. Thanks are also expressed to the highly educated Prof. Dr. Budi Agus Riswandi, S.H., M.Hum and Dra. Sri Wartini S.H., M. Hum., Ph.D. as lecturer for supporting courses for this journal. Likewise, thanks are also expressed to friends who cannot be mentioned one by one, who have contributed suggestions and thoughts, so that this scientific paper is completed.

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