VARIOUS TYPES OF COMPULSORY LICENSING UNDER THE PATENT ACT, B.E. 2522 (A.D.1979) WITH THE ACCESS TO PHARMACEUTICAL PRODUCTS OF THAI PEOPLE

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Abstract - At present, Thai people often get sick from severe diseases where the ongoing treatments are required, and the costs of medicines and treatments are high such as AIDS, cancer, coronary artery disease, diabetes, high blood pressure, etc. The costs of treatments for the mentioned diseases are opposite to income of Thai people living in Thailand, which is a developing country. The main income of the country comes from the production of agricultural products. Therefore, the income of the Thai population is low to moderate. Meanwhile, patent, process, and invention protection is widespread and serious, especially patent in type of pharmaceutical products and medical instruments. Such protection provides the exclusive right to the patentee to manufacture, use, sell, offer to sell, or import the pharmaceutical products into the kingdom pursuant to the patent, and allow the patent holder or the operator to be a monopoly to the pharmaceutical products and medical instruments. When the pharmaceutical manufacturer's company has no market competitors, the company can set the pharmaceutical price as high as it is desired; As a result, Thai people cannot afford the costs of medicines and access to the treatment accurately; hence, it leads to the premature death. This research is, therefore, a study to investigate the solution of market monopoly by using compulsory licensing over the Pharmaceutical Product Patent. This is an important mechanism under the Patent Act, 1979 to govern compulsory licensing according to the law, to promote the pharmaceutical access policy, public health, and to improve quality of life of Thai people.

Index Terms - Compulsory Licensing, Pharmaceutical Products, Patent Act, B.E. 2522

I. INTRODUCTION

Currently, Thai population often got sick and has a high mortality rate due to the lack of access to medicines and effective treatment processes. According to the report from Bureau of Policy and Strategy, Ministry of Public Health, the mortality rate of the Thai population in 2015 is categorized according to the major circumstances towards the 100,000 population as follows: All types of cancers: 112.8 people per 100,000 population, Stroke: 43.3 people per 100,000 population, Pneumonia 42.1 people per 100,000 population, ischemic heart disease 29.9 people per 100,000 population, accident from land transport 22.3 people per 100,000 population, Diabetes 19.4 people per 100,000 population, liver related diseases 16.0 people per 100,000 population, Chronic lower respiratory tract disease, 13.5 people per 100,000 population, all types of Tuberculosis 9.4 people per 100,000 population, and Acquired Immunodeficiency Syndrome (AIDS) 8.4 people per 100,000 population. When considering from the cause of death from the above mentioned, it was found that Thai population who are sick and required medicines, there are high-priced medical instruments and equipment, and there must be a continuous treatment process in a right way. However, the costs of treatments for the mentioned diseases are opposite to income and ability to access to the medicines of Thai people (Office of Policy and Strategy, 2015) .
When considering the statistical data from the National Statistical Office, it was found that the average monthly income per Thai household in 2015 was 26,915 baht. The Thai population living in Bangkok and its vicinity (Bangkok, Nonthaburi, SamutPrakarn, PathumThani) has an average income of 41,002 baht per month per household, the Thai population living in the central region has the highest average income of 26,601 baht per month per household, the Thai population living in the south has an average income of 26,268 baht per month per household, the Thai population living in the Northeast has the average income for 21,049 baht per month per household, and the lowest income was in the northern region, where there was only 18,952 baht per month per household (National Statistical Office , 2015).

From the survey data on the expenses for treating chronic diseases in Thailand obtained from the Bureau of Strategic Policy, Ministry of Public Health, the following details were found. For End Stage Renal Disease, total patients are 30,000 patients with the annual treatment fee for 6,000 million baht, and treatment fee per person is 200,000 Baht per year. For stroke, patients are 500,000 patients with the annual treatment fee for 20,632 million baht, and treatment fee per person is 41,264 Baht per year. For diabetes, total patients are 3,000,000 patients with the annual treatment fee for 47,596 million baht, and treatment fee per person is 15,865 Baht per year. For cardiovascular disease, total patients are 4 million patients with the annual treatment fee for 154,846 million baht, and treatment fee per person is 38,712 Baht per year, and for the high blood pressure, total patients are 10 million patients with the annual treatment fee for 79,263 million baht, and treatment fee per person is 7,926 Baht per year. When

considering from the Thai population's income compared with the medical expenses, it is a heavy burden of Thai population. As a result, Thai population lack of access to the medicines and health services that are fundamental rights to every human being (Nipapun, 2015).

One of the reasons for the high price of drugs and the inadequate quantity of drugs for the population is due to the exclusive right on the market of a few operators or patentees who have received the protection under the Patent Act, BE 2522 (1979), whereby the inventor has the exclusive right to produce, use, sell, have in the possession for sale, or import the patented product. In the case of the process patent, the right to use the process under the patent to produce, use, sell, have in the possession for sale, or import the process patented product to sell in the Kingdom by using the process according to the patent. However, issuing the exclusive right to produce, use, sell, have in the possession for sale, or import the patented product to sell in the Kingdom according to the Patent of the patentee means that the patentee can control the production, and medical distribution by himself solely, and can control market without having competitors. As such, the patentee can prescribe drug prices as high as it is preferred.

From the monopoly market of the above mentioned patentee, the problem of inadequate production of medicines is occurred in response to the needs of the people, or even it is adequate, but the price is very high. As a result, poor people cannot afford to buy medicines to treat their diseases. From such problem, the Patent Act B.E. 2522 (1979) provided the provisions to solves the problems by set-off the rules to allow other people who is no the patentee to be able to use their rights upon the drug patent, or it is called compulsory licensing (CL) and drug patent, which means that the action that the state authorizes other people to use a patented drug or processed patent without the permission of the patentee, but the applicant will have to pay the remuneration to the patentee. And, when it is allowed (by the state) to use such right, the applicant has the authority to produce, use, and sell patented drugs as same as the patentee. Therefore, this research aims to study on the solution of market monopoly by enforcing the patent rights of using the various types compulsory licensing on patented drugs to increase the opportunities for Thai people to access to medicines and medical services as well as improving the quality of life of Thai people.

II. RESEARCH OBJECTIVES

1. To study the concept, theory, and evolution of compulsory licensing under the Patent Act B.E. 2522 (1979)
2. To study the effect on the access to medicines of Thai people under the Patent Act B.E. 2522 (1979)

III. RESEARCH METHODOLOGY

Research on various types of compulsory licenses under the Patent Act B.E. 2522 (1979) for the accessing to medicine of Thai people is the Documentary Research, and it is having the research methodology as follows

A. DOCUMENTARY RESEARCH

This research aims to achieve research objectives on concepts, theories, and evolution of various types of compulsory licensing under the Patent Act B.E. 2522 (1979) and the problems on the accessing to medicines of the Thai people in order to analyze, collect, suggest, and solve problems as follows. The provisions of the law relating to compulsory licensing, including the Patent Act, B.E. 2522 (1979), The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the provisions of the Patent Law relating to compulsory licensing in various countries, textbooks, legal explanation books, research articles, and Judgments of the Supreme Court relating to compulsory licensing on medicines.

B. DATA COLLECTION AND DATA ANALYSIS

When the researcher collected the data, it will be divided into 4 parts as follows:
(1) The part of legal provisions
(2) The part of descriptions from textbooks and books
(3) The part of researches and articles
(4) The part of the judgment of the Supreme Court.

When the researcher has collected the data, the following implementation shall be performed:
(1) Analyze, interpret, and provide meaning of data in the form of the explanations by reading, capturing issues, and grouping data
(2) Link the concept, expand the link, find a meaning, and find a summary

C. DATA COLLECTING PLACE

ACADEMIC INFORMATION

The research will visit the areas to collect documentary data such as textbooks, books, theses, and research papers from libraries of universities such as Thammasat University, Chulalongkorn University, SuanSunandhaRajabhat University, Ramkhamhaeng University, and The National Library where lots of important legal documents are stored.

LITIGATION DATA

The researcher will collect the documentary data such as judgments of the Supreme Court, and research articles from the libraries of various organizations such as the Office of the Council of State, The Thai Bar Association, The Office of the Attorney General,

the Supreme Court, etc. These places have numerous numbers of essential legal documents and cases.

DATA FROM INFORMATION TECHNOLOGY

The researcher will collect the data from the internet (information technology) such as theoretical information, Supreme Court verdict compulsory licensing from the website of the Information and Communication Technology Center of the Supreme Court and other websites (Tanawat Pisitchinda,2016).

IV. RESULTS AND DISCUSSION

Patent is a type of intellectual property that is required by law to allow inventors of medicines or other inventions to obtain patents, and to have the absolute right or the exclusive right to seek profits from such patented drugs, such as production and distribution. Such right shall be existed for the period of 20 years, and after that the public can take advantage of the patent. However, during the period of patent protection, monopoly production and distribution of patent owners may cause expensive or inadequate drug problems to the needs of the public. Hence, compulsory licensing is vital towards the patented drugs because the State can allow other people to use patented drugs without the permission from the patentee, but the applicant will have to pay the remuneration to the patentee. And, when it is allowed by the state to use such right, the applicant has the authority to produce, use, and sell patented drugs as same as the patentee.

When considering the Patent Act, B.E. 2522 (A.D.1979), it is found that such Act set out various types of compulsory licensing as follows:

The first type is the compulsory licensing in the case of non-utilization of patents without reasonable grounds, which means, the patentee does not carry out the production of patented drugs within Thailand without reasonable grounds until it causes a shortage of drugs or the patentee does not sell drugs under patent, or sell at too high prices or sell a small amount which cannot meet the needs of Thai people without reasonable reasons. After passing three years from the date of the patent or four years from the date of filing the patent, other persons may request to use such right under the patent to the director-general.

The second type is the compulsory licensing in the case of a patent-related claim, which means, the applicant has exercised his or her rights under the patent, and such action is thereby resulted in violating the patent rights of another. If the applicant wishes to exercise such rights, he / she may file another patent application to the director-general. However, the applicant must prove that the invention of the applicant is a technological advancement that is economically beneficial as compared to the invention of the patent application. The patentee has the right to use the patent of the applicant under the appropriate conditions of the application. The applicant cannot transfer the exercise of such right to another person; unless, it is transferred with the patent. Nevertheless, the applicant must present that he or she has attempted to obtain a patent license from another patentee by presenting adequate conditions and remunerations in accordance with the circumstances of the case, but the agreement cannot be made within a reasonable period of time.

The last type is the compulsory licensing for national interest, which means, the action that the ministry, bureau, or department has the compulsory licensing on producing and distributing product under the patent by oneself or allow others to perform such action. Thus, it is for the purpose of operating the utility business, or the necessary action to protect the country, or reserve or the acquisition of natural resources or the environment, or prevent and relief food shortages, drugs or other serious consumer goods, or for other public benefit. In the exercise of this right, the ministry, bureau, or department has to pay the patentee and must notify the patentee in writing without delay. During the war or in a state of emergency, the Cabinet is authorized to issue any compulsory licensing under any patents for the necessity to protect the country and maintain the national security by paying fair remuneration to the patentee and must inform the patentee in writing without delay.

CONCLUSIONS

From the above mentioned, the Patent Act, B.E. 2522 (1979) provides the protection for the patentee to hold the exclusive rights to manufacture, distribute or import patented pharmaceutical products. Therefore, patent companies can set their own prices without having competitors in the market. As a result, medicines are expensive and inadequate to meet the needs of the people. However, the Patent Act, B.E. 2522 (1979) specified the rules related to the compulsory licensing in various types such as the compulsory licensing in case of non-use of patent without reasonable grounds, the compulsory licensing in the exercise of rights related to other patents, and the compulsory licensing for the national interests. The state can allow other people to produce and distribute drugs according to the patent, or the state may, at its own discretion, pay such fees to the patentee to solve the problem of patent monopoly in order to have variety of medicines and adequate quantity of medicines to meet the needs of the people. Moreover, the price of drug is cheaper, and people will have the opportunity to buy drugs and access more medicines. This is to lift up the standard of public health and the quality of life of the people in Thailand in wide range.

SUGGESTION

Compulsory licensing on patented drugs allowed by the states to other people to produce and distribute drugs under the patent may dissatisfied the patentee due to less benefit he or she will have from the lesser quantity of drugs that can be sold because there are more drugs entering the market at cheaper prices. As a result, the patentee does not have a new effective drug that is patented and sold in Thailand. The Patent Act B.E. 2522 (1979) should stipulate the rules and conditions for issuing compulsory licenses. In addition, the Patent Act B.E. 2522 (1979) should provide the provision to limit the amount of money or rate of damages for the patentee who is enforced to perform according to the compulsory licensing clearly, and it must be adequate to remedy the damage to the patent. Thus, it is to encourage drug manufacturers to be confident to introduce new drugs that are effective to register for a patent and sell to Thai people in the future.

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