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ABSTRACT

Background: Drug patent system has a direct impact on the health care cost and the access of the drugs of people. Previously, the drug patent system in Thailand encounters the problems both efficiency and quality of patent approval. **Objective:** This study aims to analyze the problems and to prepare the proposals for reforming the drug patent system. **Materials and Methods:** The in depth interview and Ethnographic Delphi Futures Research were used. The sample composed of 11 experts, involved with the patent system. **Results:** The expert group agrees that the drug patent system must have balance between protecting the intellectual property and protecting the people's benefit of public health, and must be able to utilize the patent document information for developing the domestic pharmaceutical industry. The experts agree in 6 issues in proposals for reforming the patent system, including the improvement of law/regulations, enhancing of the efficiency of the patent approval system, a quality raise of considering drug patents, a patent database improvement, promoting of utilizing the patent system, and developing the efficient system to protect public benefit. **Conclusion:** Thai drug patent system should be reformed to increase the capability and transparency of the system.

INTRODUCTION

Intellectual property protection is an important tool to initiate research and novel invention and to build value-added on the products. However, overprotection may result in monopoly of knowledge that will be beneficial to the economic development and may make the products exceedingly expensive. The protection of intellectual property relating to drugs or drug patent is crucial for the development of public health in Thailand because the intellectual property protection encourages investments in research and development of new drugs. The government issues drug patents for giving the sole rights to drug patent owners to gain benefits for 20 years. However, giving the sole right to patent owner might limit drug access for some people, especially for poor people in developing country. Since the patented drug is usually expensive, the government in each country must create a balance of the protection system within its country to prevent the intellectual property protection from becoming a major obstacle to accessing vital products. It was found that, considering the invention patents in the chemical category from the past to the present, the patent system in Thailand allows the right holders, who are foreigners, to gain benefits for more than 90% [1]. There are too many patent registration demands compared to the capacity of organizations and personnel in the country. In addition, there is a problem about the quality of patents, especially with drug invention [2]. Furthermore, the proportion of pharmaceutical production in the country continuously declined from 66.1% in 1987 to 31.3% in 2010 due to the consumption of the products in the country [3]. Considering the information of technology transfer as well as research and development from the Foreign Direct Investment (FDI), it was found that the Patent Act, as amended by the Patent Act No. 2 of 1992, does not significantly result in supporting FDI in the country both in overall aspect and in the industrial sectors related directly to drugs, for example, chemical product, paper, and plastic industries up until 2008 [4]. Therefore, the drug patent protection in the past does not contribute to the new drug development and the technology transfer for drug research and development in Thailand. As a result, the pharmaceutical industry in the country has been weakened, and Thai people rely increasingly on the medicine imported from foreign countries. Therefore, the reform of the drug patent system is needed to increase the efficiency of patent registration, monitoring and fully utilizing the patent system. The reform must comply with the level of science and technology development in the country and must be balanced with the protection of the interest of consumers and society in the overall picture. This research is a qualitative research, which aims to analyze the quality of the current drug

patent system and to develop proposals for reforming the drug patent system in Thailand.

MATERIALS AND METHODS

This research is a qualitative research using the review of relevant literature and in-depth-interview, to analyze the quality of the drug patent system in Thailand. The future research technique that incorporate Ethnographic Future research (EFR) and Delphi technique altogether, namely Ethnographic Delphi Future Research (EDFR) [5], was used to develop the optimistic, realistic scenarios to reform the drug patent system in Thailand according to the opinions of experts in intellectual property.

The key EDFR procedure was performed in 6 steps as follows.

1. Determined the experts in intellectual property by purposing sample. These 11 experts are 2 academics in intellectual property, 2 executives of intellectual property and the related organizations, 2 lawyers, 2 researchers in the country, 2 representatives from the pharmaceutical company and 1 from civil society. The experts were informed of the important of their opinions and the process of EDFR.
2. Collected the opinions of selected experts in the first round of EDFR by using open-ended interview questions. The first questions focus on the current drug patent system problems in Thailand. Then EFR technique was used to clarify the desirable scenarios of drug patent system. The experts were asked to give comments on the future of the expected drug patent system. The interview was noted and recorded using a tape recorder under the consent from the experts and was taken for 45-60 min for each person.
3. Synthesized the opinion of all experts using taxonomy analysis technique. Then Delphi questionnaire with the proposals of recommendations for the drug patent system reform was prepared. Based on the opinion of all experts, the questionnaires consist of 2 drug patent system philosophy, 5 measures to reform, and 29 suggestions for patent system reform.
4. Submitted the Delphi questionnaire to the experts in the second round of EDFR. The experts were asked to evaluate the desirable and the possibility of each proposal to reform the drug patent system in Thailand. The data from the experts were analyzed for median and interquartile range (IR) to prepare the third questionnaire.
5. Delphi questionnaire were re-submitted in the third round of EDFR. These step allowed the experts to decide whether they insist their previous opinions or change their opinions to be in accordance with most experts' opinions, by showing median and interquartile range, both analyzed from the expert group's answers compared with answers of each expert in the second set of questionnaire. This set of questionnaire allows experts to know that their answers are similar or different from those of all experts.
6. The data from the third round were analyzed. The results of the study were concluded. The proposals for the development of the drug patent system in Thailand were prepared, based on the corresponding opinions of experts on 2 issues as follows:
   a. That proposal offers a future desirable, where more than 80% of experts agree.
   b. That proposal is possible for implementation, where the median must be moderate, i.e., 3 or more, and the interquartile range is 1.5 or less.

RESULTS

The Problematic Situation in the Drug Patent System

According to the review of relevant literature and the in-depth interview of 11 experts, who are involved in patent systems including 2 intellectual property academics, 2 executives of the intellectual property and the related organizations, 2 lawyers, 2 researchers in the country, 2 representatives from pharmaceutical company, and 1 representative from civil society, the problematic situation in the patent system can be collected and divided into 5 main sections as follows.

Delays in the patent approval process

Delays occur in the steps before the publication, invention examining, and patent approval. Due to the delays, some drug invention patent applications take more than 10 years for consideration. The delays can be due to the insufficient number of patent examiners for the quantity of their work, the problem about the potency of the examiners, the continuation of patent consideration of examiners, and the patent applicants themselves.

The lack of clear time frame from the Department of Intellectual Property (DIP) for each step of considering patent approval

In the process for patent consideration of the DIP, there is no defined time frame for authorities to work in each step. The only defining is that an applicant must submit the details of the invention for examination within 5 years after publication under Section 29 of the Patent Act [6]. Hence, the patent applicant cannot track the progress of the patent consideration. In addition, they do not know when the undertaking of the patent examiners will end.

Problem about the quality of the patent database

At present, the problems are the difficulty of the patent search, insufficient data, out of date data, and instability of information technology system that all have direct impacts on the Thai pharmaceutical enterprises that aim to do research and to develop new generic drug.

The lack of the efficient measure on an opposition of the patent approval

Under a Section of the Patent Act, the time frame of pre-grant opposition is defined to 90 days after the publication. Since this time frame is limited, and the information technology system of the Department of Intellectual Technology has problems, the pre-grant opposition of the stakeholders is inefficient.

Problem about the quality of the approved drug patent

Evidence from the research study [2] indicated that in Thailand there are up to 84% of new drug patent applications in which the invention details are marginally changed from

those of conventional counterparts. In addition, more than 70% of approved patents are the invention patents that have only marginal changes in invention details. The problem also includes the ambiguity of patent consideration guideline, which has a direct impact on the inventors in the country and the drug access of Thais. The trend of the situation is the same as that of several developing countries such as Argentina, India, and Brazil [7].

Proposals for the Reform of the Drug Patent System in Thailand

EDFR was used to develop the optimistic, realistic scenarios to reform the drug patent system in Thailand. The flexibility of this technique allowed the research group to get the comprehensive data for proposal development. The research group collected the opinions of experts in the first round of EDFR and developed a proposal to reform the drug patent system in Thailand on 36 issues. Then, the proposals were submitted to experts for their comments for 2 rounds. It was found that the expert group has the consensus of opinions that the proposal is desirable (more than 80% of experts agreed) on 27 issues. However, when the proposals were considered in conjunction with the consensus of opinions in possibility of each proposal (a median of 3 or more, and an inter quartile range of <1.5), there are 25 issues of proposal, where the experts have the consensus of opinions, namely, 2 issues of philosophy of drug patent system, 5 issues of measures on reform of drug patent system, and 18 issues of proposals for reform of the drug patent system as shown in Table 1.

Eleven excluded issues were 3 issues of measures on reform of drug patent system, and 8 issues of proposals for reform of the drug patent system. Of these, there are 2 issues of proposal that the experts agree with less than 50%. Those issues are upgrading the DIP to be equivalent to ministry and separating the patent office from the DIP, and work as independent entity.

CONCLUSIONS

Philosophy of the Drug Patent System

The expert group strongly agrees that the drug patent system must have balance between protecting the drug intellectual property and protecting the people's benefit of public health, and must be able to utilize the patent document information for developing pharmaceutical industry in the country. This corresponds with the opinion of Limpananont [8]. It should be emphasized that drugs are crucially important to health system, and the drug patents have direct impact on drug access. If the drug patent system does not have balance between the benefit of the right holder and public benefit, such as, having drug monopoly for too long, then there will be the formidable obstacle of vital product access [9]. However, the expert panel found that creating the balance between protecting the drug intellectual property and protecting the people's benefit of public health has only moderate possibility. Therefore, there should be analysis to find various factors that might be obstacle to achieve the established philosophy.

Measure for Evolution of the Drug Patent System

The expert panel strongly agrees with the measure for evolution of the drug patent system in all five issues, and think that the proposals with strong possibility (median=4) for implementation include having the patent database system that is actually useful, and having the supporting system that encourages entrepreneurs and researchers in the country to benefit from patent. It is found that such measures are the issue that the government sector, patent academic, generic drug manufacturer in the country, and the organization in civil society sector pay attention to. Furthermore, the Office of the National Economic and Social Advisory Council used to prepare the proposal for the mentioned issues [10], and presented it to the ministry at that time. In addition, the DIP has the policy in developing the database of patent system persistently. Hence, there is strong possibility for implementation.

Proposal for Reform of the Drug Patent System

The proposal for reform of the drug patent system is divided into 6 sectors as follows.

Improving the law/regulations concerning patent system

The expert panel agrees that the law/regulations concerning patent system should be amended to raise the standard of the drug patent system in three main issues, namely, shortening time between publication date and the submission step for invention examination, clearly defining the inventive step, and extending time of pre-grant opposition to at least 1 year. This corresponds to the proposal of Kessomboon *et al*. [11], and Nikomborirak *et al*. [12]. However, the expert panel thinks that only shortening time between publication date and the submission step for invention examination has strong possibility. It is found that several countries, such as the European Union or Philippines, define the time limit of the mentioned step to only 6 months after publication date [13].

Increasing the efficiency of the patent consideration system

The expert panel strongly agrees that there should be the developing of the formal and transparent communication channel between patent applicants and patent examiners besides mailing to shorten time to examine patents, the developing of patent application system with efficient electronic filing, and having the secured storage system. Furthermore, the DIP should clearly define the time frame for considering patent approval in each step, the same as in many countries, such as, India, the European Union, and Malaysia. The expert panel thinks that these 3 issues have strong possibility for implementation.

Raising the quality of drug patent consideration

The expert panel strongly agrees that there should be an appointment of the pharmaceutical product patent committee who do not have conflict of interest in judging and managing things, concerning pharmaceutical product patent. Moreover, the expert panel thinks that there should be the external agencies that have specialists, such as, educational institute in pharmaceutical sciences, and food and drug administration, that give opinions to drug patent approval. Also, the drug patent

Table 1: Suggestions for evolution of the drug patent system in Thailand, where the experts have the consensus of opinions

Guidelines for evolution of the drug patent system in Thailand	Opinions of the experts		
	% Agreed	Possibility	
		Median	IR
Philosophy of drug patent system			
1. Be the system that has balance between protecting the drug intellectual property and protecting the people's benefit of public health	100.0	3	1.0
2. Be the system that has balance between protecting the drug intellectual property and utilizing the patent document information for developing pharmaceutical industry in the country	90.9	4	1.0
Measures			
1. Have the efficient system to protect public benefit	90.9	3	1.5
2. Have the patent database system that is actually useful	90.9	4	1.5
3. Have the supporting system that encourages entrepreneurs and researchers in the country to benefit from patents	90.9	4	1.0
4. Have the quality patent examination system that can screen the patents that should not be grantable	81.8	3	1.5
5. Have the clear and reasonable time frame for patent considerations	81.8	3	1.0
Proposal for patent system reform			
1. Improvement of Law/Regulations in the patent system			
1.1. Amend Section 7 of the Patent Act by clearly defining the characteristics of an inventive step	90.9	3	1.5
1.2. Amend Section 29 of the Patent Act by shortening time between publication date and the submission step for invention examination from 5 years to not longer than 1 year	90.9	4	1.5
1.3. Amend Section 31 of the Patent Act by extending time of pre-grant opposition to at least 1 year	90.9	3	0.5
2. Proposal for increasing efficiency in patent consideration system			
2.1. Let the Department of Intellectual Property clearly define the time frame for considering patent approval in each step	90.9	4	1.0
2.2. Develop patent application system with efficient electronic filing which has the secured storage system	90.9	4	1.5
2.3. Develop the formal and transparent communication channel between patent applicants and patent examiners besides mailing to shorten time to examine patents	100.0	4	1.0
3. Proposal for improving the quality of drug patent consideration			
3.1. Let the drug patent examiner be specialists, such as, biopharmaceutical sciences, pharmaceutical technology, and pharmaceutical chemistry etc.	81.8	4	1.5
3.2. Let the patent examiner use the drug patent examining manual to rigorously consider patent approval	81.8	5	1.5
3.3. Appoint the pharmaceutical product patent committee who do not have conflict of interest in judging and managing things, concerning pharmaceutical product patent	90.0	4	1.0
3.4. Have the external agencies that have specialists, such as, educational institute in pharmaceutical sciences, and food and drug administration, which give opinions to drug patent approval	90.0	4	1.5
4. Proposal for improving the quality of patent database			
4.1. Make announcements to let the public be aware of the bibliographical information of the patent applications that are submitted to obtain patent in Thailand on each day	81.8	4	1.0
4.2. Determine the rule to use the company names that were trademarked with the Minister of Commerce, or to mark the English names at every time that patent applications are submitted	90.9	5	1.0
4.3. Have the system that reports the progress of each patent application accurately and timely	100.0	4	1.0
4.4. Have the full text of patent application as well as the information of any undertaking of that patent application, which are both searchable from the patent database directly	90.9	4	1.0
5. Proposal for promoting utilizing the patent system			
5.1. Have the organization that is responsible for creating the drug patent database by using the patent reporting information from drug registration applicants, the same as orange book in other countries	81.8	3	1.5
5.2. Let the patent database of the Department of Intellectual Property have drug registration information by requiring patent applicants to inform the information after getting the drug registrations	81.3	3	1.5
6. Proposal for developing the efficient system to protect public benefit			
6.1. Add the measure of post grant opposition to the Patent Act	100.0	4	1.0
6.2. Have the patent monitoring system by the academic sector and social sector, where the government sector supports budget	90.9	4	1.5

examiners should be specialists, and must rigorously use the manual for examining the patent of drug invention to consider patent approval. The mentioned manual was developed to be the guidelines for approving the patent of drug invention [14], and was promulgated since October 2013 in the proposal for raising the quality of drug patent consideration. The expert panel thinks that these 4 issues are really feasible or perfectly feasible to be implemented.

Improving the quality of the patent database

The entire expert panel agrees that there must be the system that reports the progress of each patent application accurately and timely, because the reports are important information for decision making of researchers and entrepreneurs in the pharmaceutical field on planning research and drug development. Moreover, the expert panel strongly agrees that there should be the full text of patent application as well as the information of any undertaking of that patent application, which are both searchable from the patent database directly, and the requirement of using the company names that were trademarked with the Minister of Commerce, or to always mark the English names at every time that patent applications are submitted. Also, there should be the requirement of making public the bibliographical information of the patent applications that are submitted for protection in Thailand on each day. This corresponds to the proposal of Maleewong *et al*. [2]. The expert panel thinks that those 4 issues in the proposal for improving the quality of the drug patent database are really feasible or perfectly feasible to be implemented.

Promoting the utilization of the patent system

The expert panel agrees that there should be the organization that is responsible for creating the drug patent database by using the patent reporting information from drug registration applicants, the same as orange book in other countries. Also, the patent database of the DIP must have drug registration information by requiring patent applicants to inform the information after getting the drug registrations. However, the expert panel thinks that the mentioned proposal has only moderate possibility to be implemented, since such implementation needs cooperation from many associated sectors.

Developing the efficient system to protect public benefit

All experts think that the measure of post grant opposition must be added to the Patent Act to increase the protection of public benefit. The existing measure of pre grant opposition has limitation in terms of time, which is very short, only 90 days. Hence, stakeholders cannot make opposition within the deadline [15]. In addition, all experts strongly agree that there should be the patent monitoring system by the academic sector and social sector, where the government sector supports budget. The expert panel thinks that such proposal has strong possibility for implementation.

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