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EVERGREENING PATENT: THE OBSTACLE OF THAI POOR PEOPLE FOR ACCESS TO ESSENTIAL MEDICINES

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Abstract: *The purpose of this article is to propose effective legal measures to solve problems of inaccessibility to vital drugs in Thailand, without the violation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). One cause of drug inaccessibility in Thailand is pharmaceutical evergreening patents, a strategy used by drug companies to extend the period of patent protection by minimal changes in drug formula without enhancing therapeutic efficacy. The article found that there are four causes of evergreening patents in Thailand. First, there are broad definitions of patentability requirements in the Thai Patent Act 1979. Second, there is a lack of pharmacists sufficiently knowledgeable about pharmaceutical matters to examine drug patent applications. Third, there is a lack of an effective process to oppose patent applications in the Thai Patent Act 1979. Last, Thailand has no clear prescription for revocation of the patent in the Thai Patent Act 1979. To tackle the evergreening issue, this article proposes that solutions can be found in the lessons learned from India and Brazil, two countries that implement pro-health intellectual property policies, because these countries are state member of TRIPS Agreement, like Thailand, and they adopt measures to solve evergreening patent by using the principles and loopholes that TRIPS provides to the members to take benefits to safeguard their people to access essential medicines in more effective ways than Thailand. Therefore, the solutions from such countries not only help to improve people's access to medicines but importantly, they also do not violate the obligations imposed by the TRIPS Agreement.*

Keywords: Evergreening Patent, Intellectual Property, Pharmaceutical Patent, Essential Medicines, TRIPS Agreement
Research Area: Law
Paper Type: Literature Review

1. INTRODUCTION

Almost 440,000 people in Thailand are living with HIV and some of them are at higher risk of contracting Hepatitis C. The high cost of medicines and complex access route to a diagnosis are barriers, causing a bottleneck of people waiting for the treatment.[1] To redress such problem, medicines is the most significant factor to consider. However, practically, most poor Thai people cannot access essential medicines because many drug companies attempt to use patent to monopolize drug market.[2] One tactic that such companies use is called "evergreening patent" which is a strategy used by drug companies to extend the period of patent protection by trivial changes in drug formula without enhancing therapeutic efficacy.[3] To address this problem, this article identifies the root causes of evergreening patent in Thailand and offers solutions to manage such problems through learnings from other countries that implement pro-health intellectual property policies.

2. WHAT IS PATENT?

According to World Intellectual Property Organization (WIPO), *"Patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To*

get a patent, technical information about the invention must be disclosed to the public in a patent application"[4]

From such definition, it can be seen that the purpose of patent is to encourage innovation by granting inventors a patent for their inventions in the limited period of time to have exclusive rights for taking benefits from their products. In exchange, after expiration of patent term, the invention is dedicated to the public and the producers must allow public to use or take advantages from such inventions. However, practically, some inventors misuse patents by finding ways to prolong patent protection period in order to get exorbitant profits and prevent public to take benefits from the inventions.

3. HUMAN RIGHT TO HEALTH: THE RIGHT TO ACCESS TO MEDICINE

Human rights are inherent to all people and are indispensable for living a life in dignity. One human right that is so significant for dignified life is the right to health.[5] At the international level, there are attempts to ensure that people can access to essential drugs.[6] Therefore, to promote the importance of this issue, human rights law considers accessibility to medicine as right within the sphere of human right to health [7]

In 1948, UDHR provided that "everyone has the right to a standard of living adequate for health and well-being of himself and of his family, including…medical care"[8]Nevertheless, it is just preamble which is not legally binding. But, most human right scholars agree that such document has certain legal effect in the status of customary international law which forms a part of the "International Bill of Rights."[9]

The first "truly" legally binding instrument providing for the enjoyment of the highest attainable standard of health is the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) which codified the right to health in Article 12.1, in which state parties recognize the right of everyone to enjoy the highest attainable standard of physical and mental health care, including access to medicine.[10]

In addition, in 2000, the Committee on Economic, Social and Cultural Rights (CESCR) established a duty of its member to support accessibility to medicines by stating that to achieve the goal of improving people's access to medicines, it is the duty of state members to comply with and uphold ICESCR doctrine unless they lack necessary resources.[11]Hence, to guarantee the minimum standard of health care for all people, the encouragement from the government is significant.

Another Convention related to the human right to health is called the International Covenant on Civil and Political Rights (ICCPR) which is a UN multilateral treaty. This treaty is significant as it certified the human right to health by considering it as the right to life,[12] broadening the scope of interpretation to cover basic conditions of life including access to life-saving medicines.[13]

Not only is access to medicine adopted at an international level, it is also recognized in many countries at the national level by the National Constitution.[14]To illustrate, Brazil considers accessibility to medicine in the scope of its Constitution right. Consequently, within Brazil, health is defined as the basic right of all people, thus, it is the responsibility of the state to certify this right by implementing social and political policies to support public to access essential treatments [15] including the establishment of National Health System.[16]

4. THE LINK BETWEEN PHARMACEUTICAL PATENTS AND ACCESS TO MEDICINES

When the World Trade Organization (WTO) was founded in 1994, the member nations of WTO ratified a series of agreements including those on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which set global minimum standards for protecting and enforcing nearly all forms of intellectual property rights (IPR) including patents. Such agreement linked public health to IP right by extending the scope of patent protection to medicines.

4.1 TRIPS Agreement

Ratification of the TRIPS Agreement is a condition for nations to become members of WTO. The main purpose of such an agreement is to set the minimum standard to safeguard IP rights.[17]

In the past, medicines were originally excluded from patentability since many countries needed to ensure that people could access medicines. However, this idea was changed when the TRIPS agreement was established. Article 27.1 of TRIPS, prescribes that any inventions, products or processes, in all fields of technology that are new, involve an inventive step and are capable of industrial application are patentable.[18] Such Article extended the scope of patentability to all fields of technology including pharmaceuticals. Thus, a patent can be granted to pharmaceuticals when they reach these three criteria.

Article 27.1 has some problems to consider. The problem is that it lacks clear and specific meanings of "invention" and some patentability criteria: "new" and "capable of industrial application". This makes TRIPS somewhat ambiguous and opens gaps for member states to freely interpret such definitions. In the countries that implement pro-health intellectual property policies, they apply for strong IP protection by interpreting the definitions in a strict and narrow way. In contrast, some countries take advantage of such gaps to misuse patent rights by applying excessively broad interpretations which promotes evergreening patent, as will be discussed in the following topic.

4.2 Constitution: legal shield to protect IP Rights and Public Health in Thailand

The Constitution of the Kingdom of Thailand B.E. 2560, 20th Constitution, was enacted on 6th of April B.E. 2560. It considers an intellectual property right as part of a property right. In Article 37, persons shall enjoy the right to property and succession. The extent and restriction of this right are provided by law.[19] Whereas, health rights are safeguarded in Article 47 by guaranteeing that persons have the right to public health services provided by the State. Indigent persons have the right to receive public health services from the State free of charge.[20] Furthermore, Article 55 imposes the State's responsibility to certify that people receive efficient public health services universally.[21]

Theoretically, the Constitution protects both rights to property and right to health. Nevertheless, practically, the protection of both rights is asymmetrical. It seems that the property right (IP right) is better protected than rights to health, negatively affecting public health in Thailand. The causes of the problem will be analyzed in detail later.

5. EVERGREENING PATENT: THE CAUSE OF INACCESSIBILITY TO MEDICINES IN THAILAND

Evergreening Patent or endless patent is a practice whereby pharmaceutical companies extend the patent protection of a drug by obtaining additional 20-year patents for minor modifications or other iterations of the drug without necessarily enhancing the

therapeutic efficacy.[22] Such patent has negatively affected many countries around the world, especially developing countries that have a limit to the advances of technology and lack resources for pharmaceutical research and development (R&D).[23]

There are many methods to be evergreening patent. For examples, companies may apply for patents when they combine two old medicines together without therapeutic breakthroughs which are called "new combination". Another one is called "new composition" that new composition may change the original medicine to make it more liquid without therapeutic improvement. These changes are used by companies to claim a new patent application. In additions, the discovery of new uses in treatment for old medicines may lead to abusive patent applications as new medicines.[24]

International pharmaceutical companies often use these strategies to monopolize the drug market to force people buying vital drugs in expensive price. Moreover, it also a barrier for generic drug manufacturers to use the medicine of which the patent has almost expired to produce generic medicine to sell and compete to lower drug price.[25] For example, Revlimid's price is at $125,000 per year of treatment. Celgene, a drug producer, has sought 105 patents on Revlimid by minimal variation, most of them have been granted. These can prolong its monopoly until 2036 and block other generic firms from entering the market.[26]

There is a study by a group of "IP and access to medicines academics" with joint support by the Health Systems Research Institute in Thailand and DIP (Department of Intellectual Property of Thailand) that claims across a period of 11 years, 2000 to 2010, a staggering 84% of patent applications in Thailand were examples of evergreening, and 74% of patents granted also fell into that category.[27] For example, Atazanavir, Aids drug, sought to prolong the patent protection period by only combining its original patented drugs to make a new version and change the form to use the medicine without therapeutic improvement. If such patent application is granted, it could extend the life of Atazanavir patent to 2028 from 2017.[28] This part will analyze four causes resulting in an evergreening patent in Thailand.

5.1 The broad definitions of patentability requirements in Thai Patent Act

The first one is that patentability requirements are defined broadly in the Thai Patent Act 1979, which benefits the evergreening patent. Because Article 27.1 of TRIPS lacks clear and specific meanings of patentability criteria, it only imposed that inventions can be patentable if they reach the criteria of "novelty", "inventive step" and "industrial application".[29] Hence, this leaves a gap for state members to define the meaning of such criteria in their own way. In the Thai Patent Act 1979 amended in 1992 and 1999 (hereinafter "Thai Patent Act"), it defines the patentability criteria in Article 6 - 8 of the Thai Patent Act. According to Article 6, the invention is new if it does not form part of the state of the art.[30] Although Article 6 attempts to clarify the meaning of the state of the art by categorizing inventions that are considered as form part of the state of the art into five groups[31], these may not cover medical products which were produced by evergreening strategy. To illustrate, companies may apply for patents when they combine two old medicines into what is called combination for the convenience of patients and then give a new name to this medicine. The combination medicine may be new under the meaning of Article 6 because it was not widely known or was not described in a printed publication or the patent was not granted to it in foreign countries.

In Article 7, the invention involves an inventive step if it is not obvious to person ordinary skilled in the art.[32] Looking at the Article, it seems that this Act defines patentability criteria in wide meaning which allows the Department of Intellectual Property (DIP)'s officials interpret the meaning in a broad scope. If drug firms claim they had to introduce

complex or speculative derivative products, which are often only minor changes to the original drugs, in order to produce better results for patients and only this firm can produce such medicine, DIP may grant patent to the new product since the broad meaning of "inventive step" can allow drugs which were produced by evergreening strategy be patentable.

5.2 The lack of pharmacists who are sufficiently knowledgeable about pharmaceutical matters to examine drug patent applications

The second most significant cause of evergreening is the lack of pharmacists who are sufficiently knowledgeable about pharmaceutical matters to examine drug patent applications.[33] According to Part II of the Thai Patent Act, it imposed the responsibilities of the DIP officials to examine patent application whether it meets the patentability requirement.[34]To examine and grant drug patent applications, it is compulsory for the officials to have specific knowledge about drug formulation. However, practically, there are no pharmaceutical experts working in such processes. There is an example case related to a drug formula developed by using "emulsion form" which is normally known in the pharmaceutical field as lacking new knowledge. Because of having only general scientists who lack specific knowledge to examine patent applications, the patent was granted to this drug.[35]

5.3 The lack of effective process to oppose patent application

The third most significant cause of evergreening patent is a lack of effective processes to oppose the patent application. According to Article 62 of the TRIPS Agreement, its members can oppose patent applications in order to prevent the problem of invalid patents including evergreening patents.[36] Nevertheless, there is no specific provision regarding opposition proceedings in such agreement. Thus, it opens the way for a state member to select their own reasonable opposition system.[37] A pre-granted opposition system is used in Thailand as stating in Article 31 of the Thai Patent Act. It states that any person may oppose a patent application within 90 days following the publication of application if the application is deemed not to comply with the patentability requirements.[38] However, it seems that restricting only 90 days for patent opposition is insufficient and unreasonable since it is stated in Articles 62 and 41 of TRIPS that the opposition procedures shall not be unreasonably time-limited.[39]According to the AIDS Access Foundation, the pharmaceutical manufacturing process is complicated. In order to prepare reliable evidence to challenge patent applications, the opponent needs to know and understand drug formula requiring time and help from pharmaceutical experts,[40]therefore, 90 days is insufficient to prepare reasonable evidence to oppose the patent application.[41]

5.4 The problem of unclear prescription to revoke patent in Thai Patent Act

The final cause of evergreening in Thailand relates to lack of clear prescription to revoke a patent through the Thai Patent Act. Due to Article 32 of the TRIPS Agreement needing opportunity for judicial review of any decision to revoke a patent, Thailand implements Article 54 of the Thai Patent Act to approve such Article.[42]Article 54 allows interested persons to submit a petition to the court to cancel an invalid patent.[43]However, this Article is problematic since the law fails to clearly impose prescription to use this right. Thus, in trying to solve this problem, a judgment of Thai Supreme Court 475/1994 stated that due to lack of specific prescription within TRIPS and the Thai Patent Act, the court would apply prescription in general law, 10 years, which is the prescription in Thai Civil and Commercial Code to solve this vagueness.[44] However, this essay disagrees with this judgment because although there is no provision provides specific prescription to revoke the patent in TRIPS,

Articles 62 and 41 of TRIPS states that revocation procedures shall not be unreasonably time-limited. In this case, the duration for patent protection in Thailand is 20 years, while the prescription is only 10 years. It means that if the prescription expires, nobody can ask the court to revoke patent although this patent is evergreening. This is an unreasonable procedure making patentee gains wrongful monopoly until the patent expires.[45]

6. LESSONS FROM INDIA AND BRAZIL: THE WAYS TO IMPROVE ACCESSIBILITY TO MEDICINES FOR THAILAND

6.1 The Republic of India

Since India was aware that such protections would render the country undue suffering from inaccessibility to medicines, pharmaceutical products and processes are not protected by the Indian Patent Act 1970. However, because of economic pressure from the United State, India had to accept TRIPS resulting in the amendment of Indian patent law regime.[46] Being a member of TRIPS, India had to make a patent available for any invention including pharmaceutical products and processes, but also to extend the period of protection to 20 years. Nevertheless, India ingeniously decided to use the benefit from a 10-year- transitional-period in order to gradually implement its obligation to introduce more extensive IPR protection, including protection for medicines.[47] In contrast, Thailand did not opt for this benefit. The delay to implement TRIPS benefited India significantly as it used this time to develop its domestic generic drug manufacturing capability before the transitional period terminated, producing essential medicines to sell at low prices.[48]

However, as the transition period expired in 2005, India was further instrumental in mitigating the problem of drug inaccessibility by implementing three strategies to prevent the misuse of patent rights.[49]

6.1.1 India implements more strict and narrower patentability standards than Thailand to prevent evergreening patent

As Article 27.1 of TRIPS opening a gap for state members to interpret TRIPS patentability requirements, India implements more strict and narrower patentability standards than Thailand. To illustrate, the Indian Parliament established section 3(d) by way of the 2005 Amendment to the Patents Act, 1970. Section 3(d) excludes the derivatives, salts (trivial tweaks) to the known compound as not being inventions under the Act. [50] Moreover, The Supreme Court of India ruled Section 3(d) to be constitutionally valid and clarified that in order to get a patent over derivatives of a known compound; the applicant must present that the said derivative results in enhanced therapeutic efficacy as compared to the known compound. Accordingly, to overcome Section 3(d) provisions, the applicants must establish therapeutic efficacy by way of sufficient clinical evidence.[51] Medicines which are produced by only changing the form of existing patented drugs without increasing their efficacy cannot be patentable since this is insufficient to reach the requirement of "new" and "inventive step". This Act narrows down the scope of protection to prevent broad interpretation resulting in evergreening patents.

According to a remarkable Novartis case, in 2005, Swiss pharmaceutical company, Novartis, filed a patent application for life-saving cancer medicine, Glivec, in India. Chennai Patent Office rejected the application under section 3(d) because the drug was slightly a different version of its 1993 patent for Anti Leukaemia drug. The company only changed the form of the same substance. Novartis decided to challenge such a decision.[52]Finally, Indian Supreme Court held that using "imatinib-mesylate" in "beta-crystalline" form without increasing "therapeutic efficacy" was insufficient to fulfil novelty and inventive step criteria;

therefore, a patent cannot be granted to this drug. In such case, "efficacy" in section 3(d) was interpreted as "therapeutic efficacy" by the Supreme Court when considering subject-matter of the patent which was medicinal value product. The Court found no evidence to identify that the beta-crystalline form of imatinib-mesylate has superior therapeutic efficacy. The Court further said that the purpose of the patent system is to discourage the extension of the patent after the expiration of the patent term so that other companies can manufacture and market the drug in lower price.[53] The amendment of Patent Act was intended to prevent evergreening patent, provide easy access to the people of India for life-saving medicine and discharge their Constitutional obligation of providing health care to its people.[54] Such a sentence was important because it added further requirement, enhanced therapeutic efficacy, to the traditional criteria of novelty and inventive step when deciding whether the medicine can be patentable to protect public health in India.

6.1.2 India has implemented an effective patent opposition system to prevent evergreening patent

Due to allowing TRIPS state members to adopt their own reasonable opposition system, India has implemented an effective patent opposition system. Differently from Thailand, which has only pre-grant opposition system, the Indian Patent Act in section 25 has provided both pre and post-grant opposition system.[55] The pre-grant opposition allows "any person" to file an opposition depended on 11 reasons before granting the patent, whereas, post-grant opposition allows any "person interested" to file opposition based on the similar grounds before the expiry of 1 year from date of publication of allowance of the patent.[56] The meaning of "Person interested" is persons researching in the same field of patented products and organizations with an interest in manufacturing products related to patented products.[57] When comparing with Thailand, this system provides more options and a longer time period than the Thai opposition system to challenge invalid drug patent. Therefore, this system helps to increase barriers for preventing drug manufacturers from taking patent protection by using the evergreening tactic.

6.1.3 India has an effective patent revocation system to demolish evergreening patent

The lack of provision in TRIPS identifying specific prescription for patent revocation allows state members to implement their own reasonable time-period for patent revocation. Unlike Thailand that limits time-period to only 10 years for an interested person to petition the Court to cancel an invalid patent, section 64 of the Indian Patent Act allows interested persons to file a petition to the High Court for revoking patent at any time post award of the patent.[58] Thus, it can be seen that section 64 makes Indian patent examination more effective than Thailand since it has a longer time to revoke invalid/evergreening patents. Moreover, such section makes the patent examination more strict than Thailand because although the opponents cannot use pre and post-grant opposition due to the expiration of the time-limited in section 25 (provision related to patent opposition), section 64 can be used to petition the court to cancel the evergreening patent at any time during the entire life of patent protection increasing the level of examination to destroy drug patent that using evergreening strategy.[59]

6.2 The Federative Republic of Brazil

Originally in Brazil, pharmaceutical products and process were excluded from patent protection.[60] However, due to economic pressure from the United State, Brazil needed to implement TRIPS in order to provide patent protection for pharmaceutical products and processes. When TRIPS was initially adopted in Brazil, it harmed the country's drug-manufacturing capacity because it increased barriers for generic producers to produce medicines at lower prices.[61] Nevertheless, since the TRIPS Agreement provided some

loopholes for state members to take advantage to protect its public health, Brazil used such loophole to adopt measures to prevent evergreening patent to protect public drug accessibility.

6.2.1 Brazil implemented a pre-grant opposition system by imposing pharmaceutical experts to review drug patent applications before granting patent

Because TRIPS allows state members to choose their own reasonable opposition system and Articles 8.1 and 8.2 of TRIPS allow them to adopt measures to protect public health from patent misuse, Brazil implemented a pre-grant opposition system by imposing pharmacists to review drug patent applications before granting patent – a measure to prevent evergreening patents. According to Law no.10.196/2001, it set new patentability requirement for drug patent applications by requiring approval from the National Agency of Sanitary Surveillance (ANVISA) before the Brazil Patent Office (INPI) grants patents.[62] ANVISA which has pharmaceutical experts has the power to determine whether drug patent applications present any health risk as a result of using a substance that is prohibited in Brazil. In additions, ANVISA has rights to issue its opinion with patentability analysis in cases where applications relate to pharmaceutical product or process of interest to the Unified Health System (SUS) to aid INPI's technical examination.[63] This system helps to restrict the use of the evergreening patent by requiring pharmaceutical experts to examine patentability requirement and report to INPI before awarding patents.

7. PROPOSED SOLUTIONS FOR SOLVING EVERGREENING PATENT FOR THAILAND

To redress the problem of the evergreening patent in Thailand, there are four solutions proposed.

7.1 Patentability requirements in the Thai Patent Act should be amended

Considering Indian as a role model, patentability requirements in the Thai Patent Act should be amended by adding further criterion that new uses/forms of known substances cannot be patentable unless their therapeutic efficacy is enhanced. Because Article 27.1 of TRIPS opens gaps for state members to interpret their own TRIPS patentability requirement, Thailand should adopt the Indian patentability criteria to narrow down the scope of patent protection in the Thai Patent Act and establish more rigorous criteria to prevent patent applications that cannot show novelty and inventive step.[64]

7.2 A pharmaceutical patent application review committee consisting of pharmaceutical experts should be established and enshrined within the Thai Patent Act

Due to allowing state members to adopt a measure to protect national public health from patent misuse by Article 8.1 and 8.2 of the TRIPS Agreement, a pharmaceutical patent application review committee comprising of pharmaceutical experts should be established in the Thai Patent Act to review drug patent applications before awarding patents. One cause resulting in the evergreening patent is the lack of pharmaceutical expert oversight to review drug patent applications.[65]

To address this problem, Thailand should use Brazil as a model because before INPI grants a patent, it requires ANVISA, which has pharmaceutical expertise, to issue an opinion about patentability. This level of analysis through technical examination aides INPI to grant the patent. However, it is suggested that ANVISA has two limitations. The first is that the criteria for examining patent application under ANVISA are never clear to applicants because ANVISA has never published examination guidelines.[66] To protect applicant rights and to establish a transparent system, the guidelines should be clear and accessible to all applicants

if this solution is applied in Thailand.[67] Second, ANVISA's authority is limited to giving an opinion of patentability analyses to INPI only for drug patent applications containing products or processes related to the Unified Health System (SUS).[68] It means that ANVISA cannot review patentability criteria in drug patent applications that are not related to SUS because INPI also has the expertise to review drug patent claims; thus, to avoid double patentability analyses, ANVISA's power is limited to applications involving SUS that have a working relationship with ANVISA.[69] Such oversight is different from Thailand, where the Thai Patent Office lacks the expertise to review drug patent applications. Therefore, before the Thai granting of a drug patent through the Thai Patent Office, the pharmaceutical patent application review committee should have authority to examine all drug patent applications to guide the patent office in demolishing evergreening patents.[70]

7.3 Thailand should amend its patent opposition process to increase level of examination of patent applications

Because TRIPS upholds the use of patent opposition to prevent invalid patents including evergreening patents, Thailand should amend its patent opposition process to increase the level of examination of patent applications by using the Indian pre and post-grant opposition system.[71] The Indian opposition system is suggested as suitable for Thailand because it not only provides more channels and a longer time-period both before and after granting a patent to oppose evergreening patents, but it seems to reasonably balance the protection between the rights of drug patentees and the interests of public health. By example, during the pre-grant opposition period, it allows "any person" to help society to oppose patent applications that are likely to be evergreening in order to prevent a negative effect on the national public health. Meanwhile, in the post-grant opposition period when the patent has already been granted, it prevents persons who are not directly involved in the same filed of patented product from interfering with the rights of patentee by limiting those who can oppose the validity of the patent to "persons interested", such as person researching in the same field of patented product.[72]

Nevertheless, Indian post-grant opposition has limitation to consider because after receiving notice of opposition from the opponents, the Controller General of Patent and Opposition Board take a long-time process in the investigation to make redress. Thus, the longer the process is, the longer the patentees of invalid patents can enjoy their wrongful monopoly because they are still protected by the Patent Act during the examination process. To solve this issue, when implementing this measure in Thailand, the investigation should be shorter by avoiding complex and unnecessary procedures.[73]

7.4 The Thai Patent Act should be amended by adding clear and reasonable prescription for interested persons to request the court to cancel invalid patents

In order to resolve the problem of vague prescription to petition the court to revoke patent, Thai Patent Act should be amended by adding clear and reasonable prescription for interested persons to request the court to cancel invalid patents which should not be restricted to an unreasonable-10-year-period since nobody can use this right to revoke a patent after this period expires, although it is evergreening patent. Using India as a role model, the prescription should be extended to the entire life of patent protection, so that evergreening patent can be revoked any time after the grant of the patent.[74] This will strengthen the examination to demolish evergreening patent and does not unreasonably limit the time for interested persons to revoke them which conforms to Articles 62 and 41 of the TRIPS Agreement. In additions, this Indian patent revocation period is compatible with the patent revocation system in many TRIPS members such as Australia[75]UK,[76]and Japan[77].

However, to prevent double examination between post-grant opposition and revocation of the patent, Thailand can learn from Indian Patent Act by imposing that patent revocation cannot be sought once proceedings for post-grant opposition have been initiated and are pending.[78]

8. CONCLUSION

Due to Article 27.1 of the TRIPS Agreement extending the scope of patent protection to pharmaceuticals, it raises concern for many countries that pharmaceutical patents may be barriers for their people to access vital medicines. As a member of TRIPS, Thailand was required to amend its patent law to award a patent to medicine. Although the Thai Constitution certifies the right to health, Thailand still experiences a problem of inaccessibility to medicine caused by pharmaceutical evergreening patents. To remedy this problem, Thailand should take advantage of the principles, and loopholes that TRIPS provides to the members to protect its national public health in effective ways by learning from India and Brazil.

Because Article 8.1 and 8.2 of the TRIPS Agreement allows state members to implement appropriate measures to protect their public health from patent misuse, Thailand can learn from Brazil by establishing a pharmaceutical patent application review committee consisting of pharmaceutical experts to avoid granting patents to drugs produced by the evergreening strategy.

In additions, because of no specific definitions of patentability criteria in Article 27.1 of TRIPS, Thailand can use this loophole to define such criteria strictly to narrow the scope of patent protection to prevent evergreening patents by learning from India.

Moreover, because Article 62 and 32 of TRIPS allows members to provide patent opposition and patent revocation system to protect their public interest from evergreening patents, Thailand can learn from India by amending its opposition and revocation system because India provides more channels and reasonably longer time period than Thailand for opponents to use these rights to challenge evergreening patents.

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[31] Article 6 stated that *"an invention is new if it does not form part of the state of the art. The state of art also includes any of the following inventions:*
(1) an invention which was widely known or used by others in the country before the date of application for the patent;
(2) an invention the subject matter of which was described in a document or printed publication, displayed or otherwise disclosed to the public, in this or a foreign country before the date of the application for a patent;
(3) an invention for which a patent or petty patent was granted in this or a foreign country before the date of application;
(4) an invention for which a patent or petty patent was applied in a foreign country more than eighteen months before the date of the application and a patent or petty patent has not been granted for such invention;

(5) an invention for which a patent or petty patent was applied for in this or a foreign country and the application was published before the date of application."

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