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EDITOR'S NOTE

This year marks the tenth anniversary of the Thammasat Business Law Journal. It has been a long journey since the publication of our inaugural volume in 2010. As its new editor-in-chief, I am very pleased to introduce this latest edition of Thammasat Business Law Journal, which comprises 12 articles covering a wide variety of contemporary legal issues.

The publication of this volume would not have been possible without invaluable contribution from many individuals to whom I express my sincere gratitude. In particular, I would like to thank all contributors for their commendable works, all readers for their time and insightful comments, and all members of the Advisory Board and the Editorial Board for their continuing support.

Last but not least, my heartfelt appreciation goes to all members of the managerial team whose work is literally vital to the accomplishment of this volume, especially, Ms. Kanyarat Muanthong and Mr. Pontakorn Rojanawit, who have been in charge of the process from the beginning to the end, and Mr. Norachai Supparomsri and Ms. Pimtawan Nidhi-u-tai, who have worked tirelessly on proofreading and formatting.

Amnart Tangkiriphimarn
Editor-in-Chief
Thammasat University

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PRACTICAL PROBLEMS IN THE IMPLEMENTATION OF SECTIONS 308 AND 309 OF THE THAI CIVIL PROCEDURE CODE*

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Abstract

This article examines the practical problems in the implementation of sections 308 and 309 of the Thai Civil Procedure Code (CPC), as amended by the Act Amending the Civil Procedure Code (No. 30) B.E. 2560 (2017) that repealed and replaced "Title II – Execution of Judgments or Orders" in its entirety. The new law brought legal enforcement against intellectual property (IP) and intellectual property rights (IPR) into light by recognizing the same under the newly enacted provisions. Despite this, it transpired that the new sections 308 and 309 CPC, as well as the relevant provisions under Title II, are inadequate to tackle the problems identified. Such problems include, *inter alia*, an attempt to locate IP and IPR that have no physical form, the court that truly has jurisdiction to oversee the execution process against IP and IPR, price valuation and sale, as well as a licensing agreement that might have been existed and attached to the IP and IPR, or the goods associated to or bearing trademark or tradename of the judgment debtor. Because of the foregoing, this article then applies a comparative study to examine how other countries, in which the enforcement against IP and IPR has already been in force, may solve the issues. In this regard, UK law on

* This article is summarised and rearranged from the thesis "Practical Problems in the Implementation of Sections 308 and 309 of the Thai Civil Procedure Code", Faculty of Law, Thammasat University, 2019

the legal execution of judgment against IP and IPR will be studied and used comparatively to provide the possible improvements and/or solutions to the implementation of sections 308 and 309 CPC. UK law is chosen due to its long establishment of legal concepts in the execution of judgment against IP Rights and the number of cases available for comparative study. The analysis shows that UK law provides more flexibility in terms of power of the courts to supervise the enforcement process and an appointment of a receiver with broader authorities to handle the collection and disposal of IP and IPR to the best interest of all parties. This can be adopted into Thailand by amending the relevant provisions in the CPC.

Keywords: Practical Problems, Implementation, Legal Execution, Intellectual Property, Intellectual Property Rights, Section 308, Section 309, Civil Procedure Code

1. Introduction

On 5 September 2017, the Act Amending the Civil Procedure Code (No. 30) B.E. 2560 (2017) ("**Act**") came into force.

Among other amendments, the Act repeals "Title II – Execution of Judgments or Orders" in its entirety and replaces the same with an improved version. The grounds for promulgation of the Act are to ensure that the law relating to the execution of judgments and orders is suitable for the present economic and social circumstances and to try expediting the then time-consuming and regularly delayed legal execution process.[1]

The Act includes, *inter alia*, the recognition of legal execution against a judgment debtor's IP and IPR (collectively "**IP Rights**") and the rights of similar nature or relating to the IP Rights.

Despite the visionary movement, this development merely touches the surface of the problem by recognizing, under the general principle of law, that IP Rights are intangible assets that (i) have commercial value; (ii) could be appropriated; and (iii) could also be the subject of legal execution.

Specifically, the Act deploys the brand new sections 308 and 309, which endorse a judgment creditor's right to seize a judgment debtor's patent, right to apply for patent, registered and unregistered trademarks, copyright, tradename or brand, and other related rights or the rights of similar nature, for further liquidation through public auction. These sections do not however prescribe the details on how to proceed with the legal execution against IP Rights through to the end of the process.

The lack of clear directives has led to the practical problems on, among other things, an attempt to locate the IP Rights, the court that has jurisdiction to oversee the execution process, price valuation and sale, as well as a licensing agreement that might have been existed and attached to the IP Rights, or the goods associated to, or bearing trademark or tradename of, the judgment debtor.

[1] Act Amending the Civil Procedure Code (No. 30) B.E. 2560 (2017).

This article will focus on the above practical problems and how to improve the same.

UK law on the legal execution of judgment will be comparatively relied upon to provide the possible improvements and/or solutions to the implementation of sections 308 and 309 CPC.

2. Sections 308 and 309 CPC

Section 308 CPC is designed for the seizure of the registered IP Rights, e.g. patents, trademarks, or any other associated rights and the rights of similar nature. This can be done by way of notifying the judgment debtor of the registered IP rights that have been seized and thereafter have a registrar or other competent official puts such seizure on the official record.

Unlike section 308, section 309 is designed to cope with the seizure of unregistered IP Rights, e.g. unregistered trademarks, copyright, rights to apply for a patent, tradename or brand, trade secrets, and any other associated rights and the rights of similar nature.

The seizure of unregistered IP Rights can be done by way of notifying the judgment debtor without the need to involve a registrar or any other official, given that there is no official record to be updated.

3. Practical problems in the implementation of sections 308 and 309 CPC (comparing to the laws of the United Kingdom)

To apply the new sections 308 and 309 CPC, there are a few issues that need to be addressed. These issues are, in the Author's opinion, keys to further development of the two provisions and the legal execution against IP Rights.

3.1. Jurisdiction of enforcement

In Thailand, the court that has power to determine the execution measures, decide, or issue an order on the matters relating to the execution of judgment, is the court that has tried the case in the first instance.[2]

As Thailand only allows registered and unregistered IP Rights to be seized and sold through public auction, it is therefore important for the judgment creditors to know their whereabouts in order to try enforcing the judgments. Nonetheless, IP Rights does not have physical form, so it would be difficult to determine the territorial jurisdiction within which the judgment creditors may start the legal execution of their judgments.

Given that IP Rights are territorial in nature, it may follow that any court in any jurisdiction within the Kingdom shall have the power to enforce a judgment against IP Rights. However, the relevant courts and especially the executing officers may be hesitant to act, given the unclear concept as to which court should have power to proceed with the legal execution against these intangible assets.

Further, the issue will be elevated if there is a question whether the judgment debtor is the true owner of the IP Rights seized. In such event, a separate trial will be required to determine the true ownership before the execution process may continue.[3]

Assuming we adopt the concept of the place of registration, the enforcement of IP Rights must then be carried out in the Nonthaburi Provincial Court, in which jurisdiction the DIP is headquartered. This may create legal anomaly over the execution of judgment against IP Rights and it should not have been the purpose of sections 308 and 309 CPC to increase the workload of the Nonthaburi Provincial Court that has no expertise or legitimate power under the law to try IP and IP-related cases.[4]

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[2] CPC, s 271.

[3] CPC, s 323.

[4] Faculty of Law, Ramkhamhaeng University, 'Execution of Judgment on Intellectual Property Litigation', 2019, p 107.

In the UK, an execution of judgment against sophisticated matters like IP Rights may be handled specifically by a court-appointed receiver under the directions to be determined by the court on a case by case basis.

3.2. Price valuation and sale

Under Thai law, a judgment creditor must not seize or attach a judgment debtor's properties or claims more than what is sufficient to secure the performance of the judgment debt and the costs and expenses of the execution process.[5]

Following seizure, the seized property will be sold at a public auction under the supervision of the LED.[6]

The above procedures apply also to IP Rights as Thailand does not have any specific procedures in place to cope with the seizure and sale of intangible assets. This creates problems both in terms of IP valuation and how should the judgment creditors enforce their judgments against high value copyright, patents, trademarks, or brand that worth way beyond the outstanding debts.

Thailand still has no government agency capable of IP valuation. Following issuance of the Business Security Act, certain IP Rights have now been evaluated by the private sector and placed as security.[7] Despite this, the capability to perform IP valuation in Thailand is still relatively limited and should, as a priority for the purposes of improvement, be professionalized and/or made accessible to a wider public.

In the UK, the values of IP Rights are to be proposed by the judgment creditor who applies for an appointment of a receiver, together

[5] CPC, s 300.

[6] CPC, s 331.

[7] Thitiporn Wattanachai and others, Krong Wijai Gaan Bang Khap Khadee Gap Supsin Thaang Panya [Execution of Judgment on Intellectual Property Litigation] (Faculty of Law, Ramkhamhaeng University 2019) (ฐิติพร วัฒนชัย, กิตติยา พฤกษารุ่งเรืองและคณะ, โครงวิจัยการบังคับคดีกับทรัพย์สินทางปัญญา (คณะนิติศาสตร์ มหาวิทยาลัยรามคำแหง 2562)), 88.,

with the amount of income such appointment is likely to produce or otherwise obtained.[8]

To come up with the initial price, there are a number of valuation companies that are well-known in the IP valuation market. There are also several international standards for IP valuation, such as ISO 10668, DIN77100, Georgia Pacific Factors and Austrian Standard Institute standards ONORM A6800 & A6801, that can be chosen.

Despite the remarkable standard and reliability, IP valuation in the UK has never been the only solution to the execution of judgment against IP Rights. Apart from the broad spectrum of authority vested in a court-appointed receiver, UK insolvency and corporate laws also allow the relevant officials to collect payment from royalty or licensing fee, or to give license in exchange for a licensing fee, or in case of security, to foreclose the secured IP Rights in lieu of payment.[9] These alternatives provide great flexibility to the execution of judgment against IP Rights and set aside the issues as to the IP valuation. Besides, they may also remove the constraint regarding the proportion between the value of assets and the amount of outstanding debt under the judgment.

3.3. Licensing agreement and associated goods

Under the current law, there is no provision to handle the licensing agreements that might have been existed and attached to the IP Rights.

To the extent that the CPC is concerned, a party to any such licensing agreements may be deemed an interested party in the enforcement procedure[10] and the rights of that party shall not be affected by the ongoing legal execution.[11]

Considering that the current legislation merely gives authority to the judgment creditor to attach a claim the judgment debtor may have against

[8] CPR, Rule 69.3.

[9] Thitiporn Wattanachai and others (n 7) 58-62.

[10] CPC, s 287 (2), (4) and (5).

[11] CPC, s 322.

a third party,[12] it is accordingly understandable that the substance of the pre-existing arrangements would not be affected and the only increased burden would have been a direct payment the third party shall make to the court, the executing officer, or any other person designated by the court as opposed to the original payee specified in the agreement.

From the practical aspect, however, the sale of IP Rights may prove to be relatively difficult, considering that the buyer of such IP Rights will inevitably be forced to undertake the contractual obligations under the licensing agreement in lieu of the judgment debtor after purchase.

Moreover, the price of such IP Rights may be reduced significantly owing to the existence of the licensing agreement.

In the circumstances, the only purpose of legal execution, which is to get the most out of the properties sold, may not be achieved.

The UK's legal concept we may relied upon to improve the Thai legislation lies in the Insolvency Act 1986 ("**Insolvency Act**").[13]

With respect to licensing agreement, the UK insolvency law does not provide that the licensing agreement will be ended automatically upon the company entering liquidation. It follows that the parties shall continue to honor the terms and conditions of the licensing agreement pending the liquidation process. Nonetheless, the liquidator may choose to disclaim onerous property, such as a licensing agreement with disproportionate or inappropriate royalty or licensing fee. In addition, the liquidator can also disclaim an agreement which may incur more liabilities rather than rights, or that which may not be favorable or advantageous to the company.[14]

In this regard, a person sustaining loss or damage from the disclaimer will be deemed a creditor to the extent of that loss or damage and allowed to prove the quantum of the same in the liquidation process.[15]

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[12] CPC, s 316.

[13] Thitiporn Wattanachai and others (n 7) 137. 7

[14] ibid 137.

[15] Insolvency Act, s 178.

Further, another party to the licensing agreement, who is entitled reciprocally to the benefits or subject to the burdens of such agreement, may voluntarily request that the court rescinds the licensing agreement and claim for damages based on non-performance by the company in liquidation.[16]

The above applies also to the bankruptcy proceedings administered by a trustee.[17]

Given that UK law does not provide a specific period for a liquidator or a trustee to disclaim a contract, an interested party is therefore entitled to make a written request for the liquidator or trustee, as the case may be, to make a decision within 28 days following receipt of the request or any other period that may from time to time be fixed by the court.[18]

The agreement will be deemed accepted and the disclaimer can no longer be made after expiry of the specified period.[19]

It should be noted that the interested parties who can submit a written request do not include the debtor whose interests had already been transferred to the liquidator or trustee.[20]

From the Author's research, UK law does not appear to mention how the judgment creditor or receiver should handle the associated goods, such as books bearing copyrighted contents or the products made by a patented process or those carrying the brand which is the subject of the legal execution. Nonetheless, it is conceivable under the general principle of law that any such tangible assets shall not be sold or otherwise transferred together with the IP Rights to which they are attached.

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[16] Insolvency Act, s 186.

[17] Insolvency Act, s 315.

[18] Thitiporn Wattanachai and others (n 7) 140.

[19] Insolvency Act, s 178 and 316.

[20] ibid; *Frosdick v Fox* [2017] EWHC 1737 (Ch): disclaimer and strike out.

4. Conclusion and recommendations

Given the above-mentioned problems and the applicable UK laws on the legal execution of judgment against IP Rights, the Author sets out below the conclusions and recommendations on how Thai law may be amended to address the issues identified.

4.1. Conclusion

In conclusion, the research has shown that tangible and intangible assets are essentially different. While the conventional mode of enforcement, i.e. the seizure and sale of properties at a public auction, may fit for tangible properties we can determine their whereabouts and assess the current conditions to fix appropriate selling prices, the same process would turn to be difficult when it comes to the enforcement against intangible properties like IP Rights.

In the UK, alternative procedures are available for the judgment creditors to enforce their judgments against IP Rights by requesting that a receiver be appointed.

Following appointment, the receiver will then start gathering assets of the judgment debtor to satisfy the judgment and, in case of IP Rights, seize and sell, manage, collect benefits from the use of the IP Rights seized or to give license.

In a bankruptcy case, an interested party may have a liquidator disclaims onerous licensing agreement and compensates a party sustaining loss or damage from the disclamation, using the funds received from the enforcement process without the need for that party to initiate a new lawsuit.

Thailand, on the contrary, does not have any measure to tackle the issues regarding the execution of judgment against IP Rights. This makes the judgment creditors and the executing officers hesitant to act, given that their effort may eventually be nothing but an unprofitable investment.

Assuming there is a judgment creditor who chooses to act, such creditor may face the practical problems as to the jurisdictional challenge,

price valuation and sale, licensing agreement that might have been existed and attached to the IP Rights seized, or the issues with the associated goods which, although they may pose no real legal threat, could still be raised in an attempt to 'throw a spanner in the wheels' and try delaying the legal execution process.

In fact, there has been no real enforcement against IP Rights in Thailand but a number of failed attempts.[21]

To try solving the problems identified, the Author sets out below the recommendations on how we may improve the current law by adopting the UK legal concept in this matter.

4.2. Recommendations

4.2.1. Improvement on the jurisdictional issues

Although the current law provides that the court which tried the case in the first instance is the court with jurisdiction and power to proceed with legal execution, the said court may not understand the sophisticated nature of IP Rights and as such cannot find constructive solution to the matter. Further, the relevant officers may also be hesitant to act, considering the law is silent on how they should proceed with the legal execution of judgment against IP Rights.

In light of the above, we should consider allowing the judgment creditor, executing officer, or the court that tried the case in the first instance, if it sees fit, to request that the IPIT Court (i) enforces payment against IP Rights and (ii) tries a case concerning the true ownership initiated in accordance with Section 323 CPC.[22]

If there seems to be an issue whether the first court would grant the request or being proactive in seeking the IPIT Court's assistance, we may consider skipping the said voluntary process and vest in the IPIT Court the

[21] Thitiporn Wattanachai and others (n 7) 187.

[22] Section 323 CPC concerns "intervention".

exclusive jurisdiction and power over the matters to avoid further arguments.

Granting the IPIT Court the exclusive jurisdiction and power appears to be a reasonable movement, considering that the protection of IP Rights are territorial in nature and the IPIT Court is now the only court in Thailand that has power and expertise to try IP and IP-related cases.[23]

The proposed improvement could be done by way of further amendment to the CPC or, if such amendment would be difficult to achieve or does not suit the purpose of the CPC being the overarching law as opposed to a detailed operational guideline, an amendment to the IPIT Procedure Act to include the cross-jurisdictional enforcement power should suffice.

Considering that section 271 CPC, which is the general provision on legal enforcement, is already open for a specific law to kick in and determine the court with competence to oversee the legal execution process,[24] the easiest way may be to amend section 7 of the IPIT Procedure Act by incorporating a new subsection, as subsection (12), to give the IPIT Court the exclusive power and jurisdiction over the matters.

Once the IPIT Court has power to proceed, it can then issue subordinate rules to facilitate the cross-jurisdictional enforcement.

4.2.2. Improvement on the price valuation and sale

To enforce a judgment against IP Rights, price valuation is one of the key elements that cannot be avoided.

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[23] Thitiporn Wattanachai and others (n 7) 185.

[24] CPC, Section 271 (paragraph 1) provides "The court competent in the execution, which has the competence to determine execution measures under section 276 and has the competence to make a decision or issue an order on any matter relating to the execution of a judgment or an order, is the court which has tried and adjudicated the case in the first instance or as provided by law." [emphasis added]

In the UK, IP valuation has been professionalized and an acceptable standard for IP valuation will be applied to ensure the consistency and reliability of the result.

In Thailand, the government agency that currently oversees IP and IP-related matters is the DIP. Nonetheless, the DIP's scope of authorities does not cover IP valuation for the purposes of legal execution. We also have no other regulatory agency capable of doing so -- not even the LED which is responsible for the valuation and sale of properties as part of the legal execution process.

Presently, IP Rights are starting to be evaluated by private sector and placed as security under the Business Security Act. This applies also to the execution of judgments against listed securities under the Securities and Exchange Act B.E. 2535 (1992), of which prices will be evaluated by the SEC-certified private companies.[25]

That being said, it may be prudent for Thailand to allow private sector like the Valuers Association of Thailand, the Thai Valuers Association, or any other certified professionals, to carry out IP valuation in Thailand using an acceptable international standard or a standard to be prescribed by a competent authority.

With respect to the sale of IP Rights, the current law should be amended to include the alternative, court-supervised, enforcement procedures. This may include an appointment of a manager to seize, sell or otherwise manage the IP Rights that has potential to generate income, as well as to give license and collect future payments for a period sufficient to cover the judgment debt and the management fees.

In doing so, we may consider adding new paragraphs into the now existing section 336 CPC, adopting the wordings used in section 73 of the Business Security Act to make it clear that section 336 CPC applies also to the legal execution of judgment against IP Rights and clarify the extent to which a manager may perform.

[25] Thitiporn Wattanachai and others (n 7) 188.

Any such appointment and the subsequent actions of the manager should be subject to review by, and follow the directions from, the court. This is to ensure there are adequate 'checks and balances' in the activities to be done following appointment.

4.2.3. Improvement on the licensing agreement-related matters

After all, the main purpose of legal execution is to try liquidating the assets of the judgment debtors at the highest price possible to satisfy the judgment debts. Given that the current law only allows the seizure and sale of intangible assets through public auction, the merchantability and price of the same will depend significantly on their status and the benefits the buyer would gain from the purchase. For this reason, intangible assets with burdens will be harder to sell and, in any event, the prices will be relatively low.

In this regard, we may amend the law by allowing a judgment creditor and the other interested parties, e.g. another contracting party or a third party who will be affected by the non-performance of the licensing agreement entered for the IP Rights seized, to propose whether and how the pre-existing arrangement should be dealt with.

In doing so, we may include the definition of "onerous property" in the CPC and allow the said parties to request that the court continues or disclaims the onerous agreement attached to the IP Rights.

If the agreement is disclaimed, the affected party should have a right to prove the loss or damage sustained. After which, the proven amount should be deemed a judgment debt, allowing such party to enforce the same as an immediate remedy without the need to initiate a new lawsuit.

A disclaimer, if any, should be made within a fixed period of 30 to 60 days after the date on which the licensing agreement is known to the judgment creditor or a party that may be affected by the result of the disclamation.

In the process, the court may hear the judgment debtor's comments before giving order. The judgment debtor's involvement should however be

limited only to provide comments but not to choose whether the licensing agreement should be disclaimed. This is to avoid further issues as to the conflict of interest and a potential conspiracy between the judgment debtor and another contracting party in their attempt to cause delay or damage to the judgment creditor.

The order must take effect as from the date of issuance and not in any way be retroactive.

Further, although the issues are minor, it should be clear that any goods associated to the IP Rights seized are not the subject of legal enforcement against such IP Rights.

It is also important for the legislative body to contemplate the other issues, e.g. execution of judgment against securities under the law on securities and exchange,[26] bill or any other negotiable instrument,[27] shares in a limited partnership or company[28] or any other rights the judgment debtor may have against a third party[29] in order to make a constructive improvement and come up with a more comprehensive provision, addressing also the other issues which are not included in the scope of legal enforcement against IP Rights, but have or may nevertheless come to light.

[26] CPC, s 305.

[27] CPC, s 306.

[28] CPC, s 307.

[29] CPC, s 310 and 311.

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Book

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LEGAL LIABILITY FOR DAMAGE ARISING FROM DRONES*

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Abstract

Due to unavoidable interaction between humans and drones in various ways for extended period of times, these kinds of robots have been developed along with the technological advancement. Particularly, Artificial Intelligence is the technology in which its special characteristics enable the imitation of human behaviors by learning, training and analyzing input data, which results in an autonomous decision through different levels of automation without the human intervention. The increasing use of pilotless aircrafts or drones could simultaneously expose the damage caused by aforementioned autonomous systems but the existing liability regimes in Thailand are assumed to deal with damage caused by human operators and manufacturers. The author surveys different liability regimes from the United States of America (USA) and Italy including relevant regulations of European Union (EU) and suggests that the strict liability with less burden of proof is currently an appropriate liability regime and implemented acts of EU should be adopted in order to ensure the compensation for injured persons.

Keywords: Pilotless Aircrafts, Liability, Artificial Intelligence, Automation

* This article is summarized and rearranged from the independent study "Legal Liability of Damage from Drones", Faculty of Law, Thammasat University, 2019.

1. Introduction

In today's world, the use of unmanned aerial vehicles (UAVs[1]) or drones has increased to assist humans in performing defined tasks. This industry has been developed along with technological advancement of AI which enables the self-adaptive capability through learning and training under certain circumstances. As a result, UAVs could independently make its own decision without the human intervention in the UAVs operations.

In this regard, according to different levels of automation adopted with UAVs, an increasing degree of automation appears to be constantly in contrast to those of any human intervention which shall be reduced to a minimum. Various autonomous systems can be largely categorized into two models, which are semi-autonomous and fully-autonomous. The criterion for classification is the human involvement in maintaining the authority and responsibility over the operation.

According to legislation in Thailand, there is no specific legal provision for dealing with the damage caused by an autonomous system embedded in UAVs. Under Thai Civil and Commercial Code (CCC), the UAVs operator could be regarded as assumed liable person. In addition, the damage may be caused by the defect of UAVs in which the manufacturer who manufactures the vehicle containing a computer program shall also be assumed as another liable person under the Product Liability Act B.E. 2551 (PLA). Nevertheless, due to an unforeseeable and inexplicable behavior addressed by AI tools in higher level of automation, it generally causes a challenging issue for existing liability rules to find an appropriate liability model including additional measures to ensure the compensation to injured persons.

[1] The term of UAVs used in this article may not be consistent with the term used in formal instrument of civil aviation law accepted by Thailand.

2. Basic concept of Unmanned Aerial Vehicles (UAVs)

The development of UAVs has derived from the simple notion that humans would like to fly in the air like a bird, therefore, the first flying machine shall be invented with wings by imitating the action of flying bird. The design has inspired many inventors for adopting the technological innovation in manufacturing processes to ensure that the capability of unmanned flight in new models can be demonstrated. However, due to the aim to protect humans from any danger arising from the device control, the doctrine of pilotless aircraft occurs including the evolution of UAVs from primary use for military purposes to a variety of either commercial or non-commercial purposes. UAVs or drones are simply defined as unpiloted vehicles which could be essentially remotely piloted or autonomously operated with various degrees of autonomy[2]. A system designed for supporting an autonomous operation has been furtherly developed, for example, Amazon Company has launched Amazon Prime Air as the first fully autonomous UAVs for delivery services of products to customers in Cambridge, England in 2016[3].

3. Artificial Intelligence (AI)

The advancement of computer science has addressed intelligent human characteristics to UAVs which results in the capabilities of thinking, learning and making a decision for solving complicated problems in different situations. The operation of human brain shall be simulated based on input in the form of datasets and knowledges influencing its processing and a further appropriate decision made by UAVs in which it is assumed to be unforeseeable and inexplicable through machine learning processes. It could be either supervised learning program pre-determined by the

[2] Malek Murison, 'Defining Drones: What is a Drone?', (DroneFlyers, 27 August 2019) <https://www.droneflyers.com/defining-drones-what-does-drone-mean/> accessed 27 September 2020

[3] Amazon, 'Amazon Prime Air', <https://www.amazon.com/Amazon-Prime-Air/b?ie=UTF8&node=8037720011> accessed 27 September 2020

programmer or unsupervised one with more complexity but less predictability.

4. UAVs based on AI capabilities

According to the following various levels of automation based on the Society of Automotive Engineers (SAE)[4], the degree of human involvement shall be in contrast to increasing autonomous level embedded in UAVs.

(1) Level 0: No Automation

UAVs shall be operated without any degree of automation. The entire system of devices is solely under human's full manual remote control whose operator must be trained and skilled. The example of UAVs in this level are usually racing model aircrafts in which most of them do not have flight assistance[5].

(2) Level 1: Pilot Assistance

An autonomous capability shall be provided for assisting the human operator in an operational function of UAVs for mission accomplishments. However, the operation and safety function remains wholly in control of UAVs operator either acceleration or flight path. Autopilot program could be primarily supportive in navigating and global positioning satellite (GPS). For example, in case of long range of distance for purpose of detection, inspection and maintenance, UAVs operators could

[4] Miriam McNabb, 'DRONEII: Tech Talk – Unraveling 5 Levels of Drone Autonomy', (dronelife, 11 March 2019) <https://dronelife.com/2019/03/11/droneii-tech-talk-unraveling-5-levels-of-drone-autonomy/> accessed 28 September 2020

[5] Jonathan Feist, 'Buying a racing drone? Things to know before you fly', (DroneRush, 5 November 2020) <https://dronerush.com/buying-racing-drone-safety-accessories-tools-6860/> accessed 6 November 2020.

execute cruise function[6] to relieve the operator's overall concentration on the operation all times.

(3) Level 2: Partial Automation

Under certain conditions, the routine flight shall be normally automated in that UAVs have capabilities to control the operation concerning speed and altitude itself but the operator still has the important role to be in charge of ensuring safety operation regarding airspace monitor and response to any emergency circumstances[7]. The vehicle also have a built-in automated take-off and landing features. If the computer system has sensed any obstacles, the operator shall be immediately alerted about them. The author's opinion is that UAVs adopting this autonomous level cannot be fully operated by the system. Despite in automation mode applied, the aircraft must be under the operator's surveillance in any time.

(4) Level 3: Conditional Automation

Autonomously adaptive capabilities could be found in this high degree of UAVs, for example, on-board sensor shall be installed for detecting any obstacles during its flight route and the UAVs is capable of stopping its operation. However, the manual control of the operator shall be addressed to correct the device's further movement prior to its continuous compliance with the pre-determined route, for example, Amazon Prime Air which provided delivery service and also adopt sophisticated "sense and avoid"[8] function shall be fallen under the definition of this autonomous level.

(5) Level 4: High Automation

UAVs can be controlled but not required by the operator. The device needs the back-up system to be operational in case the failure of main systems. With increasing self-adaptive capabilities, the UAVs can

[6] Aeronyde Corporation, 'Self-Flying Drones: Who will be in the pilot's seat?', (Aeronyde, 28 August 2018) <https://aeronyde.com/2018/08/28/2018-8-28-self-flying-drones-who-will-be-in-the-pilots-seat-1/> accessed 1 November 2020.

[7] supra note 4

[8] supra note 4

navigate without the input from human operators by automatically diverting the flight path to avoid the interaction when facing any obstacles. The example of this kind of device is mostly used for the purposes of photography and filming to capture various perspectives of nature and forest[9].

(6) Level 5: Full Automation

Although it might be likely the futuristic model, the UAVs can operate itself under all circumstances along with moving under any conditions without any human intervention. Full automation system might be considered as authentic AI which shall include autonomous learning process from previous environmental situations by algorithm and machine learning through processing with the modification ability resulting in unforeseeable self-managed and automated operation. The physical harm of high risk of dangerous operation in high densified airspace shall be solved with this imaginable UAVs model. Unfortunately, there is no current production on this highest degree of UAVs automation[10].

According to different levels of autonomation adopted, the human intervention in the UAVs operation shall be directly decreased upon higher degrees of automation. Accordingly, this situation could demonstrate the legal significance into liability issues.

5. Foreign Laws on Liability for Damage arising from UAVs

There are different types of liability adopted with the damage caused by UAVs. The author shall classify them as fault-based and strict liability. Besides, the study shall focus on the UAVs operator and manufacturer. To this end, related liability regimes of two countries and one international organization shall be provided as follows:

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[9] AltiGator Unmanned Solutions, 'Aerial photography and filming for cinema & television' <https://altigator.com/aerial-photography-and-filming-for-cinema-or-television/> accessed 2 November 2020.

[10] supra note 4

5.1 USA

In addition to the regulations of the Federal Aviation Administration (FAA) for the UAVs weighing less than 55 pounds[11], USA adopted negligence regime as common law principles with other bigger UAVs for imposing fault-based liability. In order for the injured persons to hold the UAVs operator liable, four elements must be satisfied; namely, (1) the existence of duty of care; (2) a breach of such duty; (3) injuries caused to the victims; and (4) a causation between a breach and injuries. Although the UAVs operator owed such duty to individuals for safe operation, it becomes more complicated to recognize and assess an unforeseeable decision by fully autonomous capabilities and it shall inevitably break the causation between human operators and injuries caused.

Based on strict liability regime without fault, the UAVs manufacturer could be held liable for the damage caused by defects irrespective of the exercise of reasonable duty of care. Aforementioned defects could be divided as three categories: (1) manufacturing defects; (2) design defects; and (3) failure to instruct and warn. Unexpected outcomes beyond its original set of rules owing to the incorporation between algorithms and machine learning could cause an accident that the manufacturer shall improbably foresee or warn.

5.2 Italy

Governed by the Rome Convention of 1952, Italy extends the strict liability rules imposed to UAVs operator for the damage caused by UAVs operation[12]. Thanks to no specific liability regime, the Italian Navigation Code shall be applied for either general remotely piloted aircraft system or

[11] Federal Aviation Administration, 'Fact Sheet–Small Unmanned Aircraft Systems (UAS) Regulations (Part 107)', 6 October 2020 <https://www.faa.gov/news/fact_sheets/news_story.cfm?newsId=22615> accessed 2 November 2020.

[12] Studio Pierallini, 'Drone Regulation in Italy' (Lexology, 10 December 2019) <https://www.lexology.com/library/detail.aspx?g=68903659-fba4-47d5-bdb7-0a8a7ea3cf39> accessed 2 November 2020.

autonomous unmanned aircraft system. In order to be entitled for compensation, the injured person is required to prove the causal link between the damage caused and UAVs operation.

5.3 European Union (EU)

Even though the Regulation (EU) of 2018/1139 of the European Parliament (RCA) has given a minimum safety standard as common rules of UAVs operation, there is no any liability rules enacted for the human operator. Nevertheless, under the Product Liability Directive (PLD), UAVs are regarded as a product since they are movable properties[13]. PLD imposes liability on the UAVs manufacturer[14]. In order to claim for compensation, the person injured by the defective condition of UAVs is required to prove the damage, the defect and a causal link between the first two elements[15].

In order to ensure the compensation as result of the damage caused by fully autonomous systems embedded in UAVs, EU has subsequently implemented the recommendations[16] introducing compulsory insurance schemes among relevant UAVs parties including the necessity of compensation fund in case that the UAVs are not insured or the liable person cannot be identified along with the privilege of proportionate limited liability.

[13] Article 2, PLD.

[14] Article 1, PLD.

[15] Article 4, PLD.

[16] European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics <https://www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.html?redirect> accessed 30 September 2020

6. The Problems on the Current Liability Regime on UAVs in Thailand

Owing to a lack of specific provisions related to the liability for damage caused by automation systems in UAVs, The Thai Civil and Commercial Code (CCC) shall be applicable. However, tort law cannot be effectively enforced because it is difficult to determine the authentic cause of damage and the liable person on unforeseeable and inexplicable UAVs operation notwithstanding the relief from proving a fault of UAVs operators under strict liability regimes.

Even though being able to be regarded as the vehicle's controller who is responsible for preventing the damage caused under section 437 of CCC[17], the UAVs operator should not be considered as presumed liable person in case of the operation propelled by fully autonomous systems without any control over UAVs by the human operator.

Besides, the UAVs could also be considered as a product under the Product Liability Act B.E. 2551 (PLA) which imposes the liability caused by the defective condition of UAVs on the manufacturer[18]. Nevertheless, there are two different opinions whether the computer program operating UAVs shall be interpreted as a product for the applicability of PLA to ensure the compensation in addition to CCC. In this context, the damage could also be variously caused by machine learning including algorithm involved with the designer and developer of this intelligent science which might be considered as the direct cause of unforeseeable actions of UAVs.

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[17] Jit Setabutr, Lak Kod Mai Phaeng Laksana La Mert [Principles of Civil Law on Torts] (8th edition, Faculty of Law, Thammasat University, 2013) (จิ๊ด เศรษฐบุตร, หลักกฎหมายแพ่งลักษณะละเมิด (พิมพ์ครั้งที่ 8, คณะนิติศาสตร์ มหาวิทยาลัยธรรมศาสตร์, 2556)), p.264.

[18] Pongdech Vanichkittikul, Kham Athibai Pra Rat Cha Ban Yat Kham Rab Phit Tor Kham Sia Hai Thi Koet Khuen Chak Sin Kha Mai Plot Phai [Explanations of Product Liability Act] (Bangkok: Rungslip Printing Co., Ltd., 2009) พงษ์เดช วานิชกิตติกูล), คำอธิบายพระราชบัญญัติความรับผิดต่อความเสียหายที่เกิดขึ้นจากสินค้าไม่ปลอดภัย กรุงเทพ): บริษัท รุ่งศิลป์การพิมพ์ จำกัด, 2552)), p.5.

In order to claim for a compensation under PLA, it is difficult to prove the use or preservation of UAVs by its nature, especially for injured persons because this technical knowledge is beyond their acknowledgement which may cause them eventually uncompensated.

7. Conclusion

Currently, an appropriate liability model to be adopted for the damage caused by an autonomous system with AI capabilities is a strict liability regardless of burden of proof on misconduct which is more beneficial than fault-based ones. In order for the effective applicability under CCC, the term "controller" should cover only the case of semi-autonomous level in which the human operator has the authority over the operation. Besides, in order to ensure the compensation, the implemented approach such as compulsory insurance schemes and compensation fund recommended by EU should be adopted as well. To be concluded, this advanced disruptive technology shall be unstoppably developed and the existing liability rules might no longer be appropriate for the upcoming damage in the future.

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LEGAL ISSUES IN TENDERING PROCESS: A CRITICAL ANALYSIS OF THAI LAW AND FOREIGN LAWS*

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Abstract

The general requirement for considering a contractual formation is inevitably the offer and acceptance approach. In some cases, such approach causes some hardship in providing legal protection for the parties in the tender process. Thai courts have dealt with the contract's formation to explain the legal relationship between owner and tenderers. The courts refer to the tender process contract as the legal ground to forfeit the bid guarantee and claim damages. However, it appears that the courts grant legal protection to the owner rather than the successful tenderer by stating that there is no principal contract.

In this article, a comparative study is conducted on how other countries dealing with this specific case because of the problem. Each selected country takes a different approach in dealing with the case. Canadian legal system solves the problem with the two-contract approach, while the German legal system deals with the *culpa in contrahendo* principle. Last but not least, the Scots legal system takes a different path with the promise principle.

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Each studied approach may face theoretical problems in the Thai legal system. This article finds that the Thai court may apply the foreign legal practices or may observe some principles in the Thai Civil and Commercial Code that may solve the case, especially the promise principle.

Keywords: Tender Process, Promise, Pre-contractual Liability, Formation of Contract, Prize Competition

1. Introduction

This article aims to study the problem in the area of private law. In the area of public law, the administrative court has the power to observe the tender process for example the concession contract. The issues are whether the discretion of the public officer to reject the tender is against the law or not. The court has no difficulty to legally characterize the tender process because there is the law govern to this case[1]. While in private law, the court has to find what is the relationship between the person who made an invitation to tender ('owner') and the person who submit the tender ('tenderer').

The tender process is usually a process to procure a suitable contractor to perform the task relating to the awarded contract ('principal contract'). Usually, the tender process consists of the announcement of invitation to tender, the submission of tender document, negotiation process, the announcement of the successful tenderer and the last is the conclusion of the principal contract. The first step is to announce the invitation to tender in order to attract the interested tenderers to participate by submitting the tender documents. The tender documents shall be subject to conditions prescribed in the invitation to tender. After consideration, the owner shall announce who gets the contract. The last stage is the signing of the principal contract between the owner and the successful tenderer.

Most of the cases decided by Thai courts usually involve the last stage. The tenderer or the owner refuses to sign the principal contract. The problem is whether Thai courts can grant the damages to the suffered parties on which legal ground. The courts then deals with the tender process by stating that the tender process may create the legal obligation by means of contract ('process contract'). However, the courts face the theoretical problem with the formation of process contract. In addition, the

[1] The Decision of Thai Supreme Administrative Court no. 1/2563 (2020 A.D.). This contract was regulated by the public and private partnership B.E. 2556 (2013 A.D.)

courts grant the damages to the owner solely. The successful tenderer cannot claim the damages on the ground of process contract. The court reasons that the damages claimed by the tenderer resulting from the principal contract. However, the principal contract does not exist because of section 366 paragraph 2 of the Thai Civil and Commercial Code ('CCC'). Therefore, the tenderer cannot be claimed any damages on the ground of principal contract. It is interesting that the court does not analyze whether the tenderer may claim the relevant damages according to process contract as same as the owner do.

2. The legal characteristics of the tender process under Thai laws

As mentioned earlier, the court takes a contractual approach to legally characterize the tender process. The tender process contract is mentioned first in the Decision of the Thai Supreme Court no.931/2480 (1937 A.D.). Although the court did not analyze the formation of the process contract, the court refers to the process contract as a ground for forfeiting the bid guarantee. This remarkable case set the standard for the Thai court for dealing with the tender process.

The formation of a contract in Thai legal system is based on the offer and acceptance approach. The courts have to analyze whether the invitation to tender is an offer or not. The court decides that if the invitation to tender has the condition prescribed that the person who made the invitation to tender may cancel the tender process, or shall not be bound to establish the contract with the lowest tender or any person who submitted the tender[2]. As a result, the invitation to tender is considered as an invitation to treat. With this analysis, the submission of a tender document is considered as an offer and the announcement of a successful tenderer is an acceptance.

[2] The Decision of the Thai Supreme Court no. 2811/2529 (1986 A.D.), The Decision of the Thai Supreme Court no. 3249/2537 (1994 A.D.).

The question is whether offer and acceptance create the process contract or the principal contract. The process contract in this case is not actually established because the formation of a contract in this scenario is the principal contract. However, with the presumption of an unestablished contract in section 366 paragraph 2 of CCC. The principal contract is not concluded until the contract is in the written form.

The problem will arise when the successful tenderer denied to sign the contract or the owner cancels the tender process without specific reasons before the principal contract is concluded. Therefore, neither process contract nor principal contract does exist. As such, the person who made an invitation to tender may cancel the tender process without any liability or breach of contract even there is an announcement of a successful tenderer in case that the principal contract is not yet in written form[3].

2.1 The process contract and bid guarantee

Regarding the formation of the contract, Sotthibandhu[4] explained that the tender process contract could be considered in two ways. First, if an invitation to tender is not certain enough to be an offer, then the submission of tender documents will be considered as an offer made to a person who made an invitation to tender. The notice to award the contract that is recognized by the successful tenderer will be considered as an acceptance. As such, the principal contract is established, not a tender process contract.

However, most of the tender shall contain the condition that the awarded tenderer has to enter the contract with the owner in the written form. The principal contract is not valid until the contract was signed in written form, according to section 366 paragraph 2.

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[3] The Decision of the Thai Supreme Court no. 3550/2526 (1983 A.D.).

[4] Sanunkorn Sotthibandhu, Lak Kwam Rub pid Korn Sanya [หลักความรับผิดก่อนสัญญา] (3rd edn, Winyuchon 2005) 158 (ศนันทกรณ์ (จำปี) โสตถิพันธุ์, หลักความรับผิดก่อนสัญญา (พิมพ์ครั้งที่ 3 วิญญูชน 2548)) 158.

Second, if an invitation to tender is satisfied enough to consider as an offer of the tender process contract, it could be deemed that such an offer contain another invitation to treat for the principal contract. To be an offer, the courts have to examine the content of the invitation to tender. For example, the undertaking clause such as the condition to accept the lowest tender without the right to accept or to not accept any tenderer. If there is enough certainty, the invitation to tender shall be considered as an offer. In this scenario, submission of the tender document will be considered as acceptance for the tender process contract and also be an offer for a principal contract. The next question is whether the process contract is existed only for the owner or the successful tenderer?

The Thai court did not set the criteria when the tender process contract exists. The court refers to the liability clause prescribed in the invitation to tender as it is the tender process contract. Most of the liability clause shall provide the condition that if the tenderer fails to enter the contract with the owner or revoke his tender before the announcement of the tender, then, the tenderer has to pay the damages. In this sense, a process contract is established according to the liability clause[5].

Tingsabadh[6] has an annotation on this decision by explaining that the tender process contract should not exist because the obligation of the parties to sign the contract is not enforceable.

The suitable way for considering the tender process contract is to be as a stipulated penalty according to section 383 of CCC. Sotthibandhu[7] further analyzes Tingsabadh's comment that the parties both agree to sign the contract in written form, according to section 366 paragraph 2 of CCC. As long as the contract is not signed, the contract is not established. As such, the creation of a tender process contract is not useful as it is unenforceable for both parties to sign the contract.

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[5] The Decision of the Thai Supreme Court no. 320/2522 (1979 A.D.)

[6] Sanunkorn Sotthibandhu (n 4) 158

[7] Ibid

The court explained that the tender process contract would be established when the tenderer acknowledges that he won the contract. In contrast, Thai scholars explained that there is no tender process contract between tenderer and owner. However, the result of a different opinion generates the same result as the compensation to the owner is to forfeit a bid guarantee. Besides, there is no Supreme Court Decision to enforce the parties for concluding the contract. One of the reasons is that the damaged parties also claimed only the damages, not for the signing of the principal contract.

Apart from the process contract, the bid guarantee is one of the devices to ensure that certainty for each tenderer that they will not revoke the tender document and the tenderer who won the contract shall enter the contract with the owner. The status of the bid guarantee is depended on the legal status of the tender process. If the court considered there is the tender process contract, then, the bid guarantee shall be earnest. If not so, the bid guarantee will be considered as a stipulated penalty according to section 383 of CCC.

The court still rules that even the principal contract is not established; however, the person who made an invitation to tender may forfeit a bid guarantee, if the person who submitted the tender breaches the condition prescribed in the invitation to tender[8].

2.3. The process contract's obligation and the relating damages

Although the Thai court analyzes the tender process as a process contract, the court still does not describe the obligation according to such a contract. The court only deems a tender process contract to be the ground for the forfeit of bid guarantee. Besides, the owner may claim the damages for the different prices. However, such conditions shall be written in the

[8] The Decision of the Thai Supreme Court no. 1943/2542 (1999 A.D.).

invitation to tender[9]. Without such a condition, a person who made an invitation to tender can not claim such damages[10].

Moreover, the court also further decides that the damages resulting from the breaches of contract, such as the damages for preparing tender documents for another bidding, the consultant cost, and the damages for the delay, are the damages directly from the principal contract, not a process contract. As such, even there is a breach of the process contract, such damages can not be claimed[11].

There is a controversy between the view from the court whether the damages from the different price comes from the principal contract or a process contract. In the first case[12], the court decided that such a different price is the damages resulting from the principal contract. Therefore, when the principal contract is not established, the plaintiff cannot claim such damages. There is one case[13] the court decided that even the conditions to claims such damages contained in the invitation to tender, the court cannot grant the damages. However, it seems the court accept the first case by stating that the damages can be claimed if the invitation to tender prescribed so and called such conditions as the process contract[14].

In conclusion, the element examined by the court whether the process contract exists is the liability clause prescribed in the invitation to tender. However, this tender process contract in this sense should be the stipulated penalty rather than the actual contract. With this result, the one who only has the benefit is the owner while most of the cases, the tenderer cannot claim any damages prior to the conclusion of the principal contract.

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[9] The Decision of the Thai Supreme Court no. 320/2522 (1979 A.D.) and no.1943/2542 (1997 A.D.).

[10] The Decision of the Thai Supreme Court no. 581/2523 (1980 A.D.).

[11] The Decision of the Thai Supreme Court no. 5486/2536 (1993 A.D.)

[12] The Decision of the Thai Supreme Court no. 931/2480 (1937 A.D.)

[13] The Decision of the Thai Supreme Court no. 1418/2529 (1986 A.D.)

[14] The Decision of the Thai Supreme Court no. 1943/2542 (1997 A.D.) and no. 8194/2543 (2000 A.D.)

Principally, the unsuccessful candidate can not claim damages, which are the purchase of tender document, operation cost, legal advisory cost because the person who submits the tender is aware that he or she may or may not win the bid. Apart from the expected damages, in some cases, such as bid-rigging, unfair cancellation of the tender process, the tricky tender process for acquiring the trade for confidential information, or trade secret, the unsuccessful candidate may suffer unexpected damage. In this case, Sotthibandhu[15] proposes that the unsuccessful candidate may claim the damages as a pre-contractual liability. Another approach to this case is to claim under tort law.

However, it is quite hard to prove whether the parties willfully or negligently as the burden of proof is fall upon the claimant. It is undeniable that negotiation is the freedom of both parties, especially both parties, who are free to end the negotiation at any time. As such, it is questionable whether ending the negotiation is unlawfully or not. Also, the application of tort law in Thailand may face the problem because the meaning of unlawfully acting as prescribed in section 420 of CCC did not cover the area of the pre-contractual phase. Besides, the right protected according to section 420 is an absolute right, which is the right involve in health, body, freedom, and property[16]. Whether the freedom of contract as to ending the negotiation shall be included in the absolute right is still left to be questioned.

For all the above reasons, the court does not define the process contract as a bilateral contract that binds the tenderer and the owner. The court applies the principle of stipulated penalty that the tenderer agrees to pay the compensation if he breaches the condition prescribed in the invitation to tender. The question is that if the process contract actually exists, what the legal obligation between the parties is.

[15] Sanunkorn Sotthibandhu (n 4) 162-164.

[16] ibid200.

2.4 Prize competition and tender process

The prize competition contains the condition specified by the method and the decision-maker to decide who will win the prize. Prize competition also requires a specified period of time for entering the contest, which differs from the promise of reward. Without a specified period of time, the prize competition is invalid, according to section 365. The prize competition shall be effective when such promise is announced publicly[17].

The invitation to tender generally specified the evaluation method, the period of time for submitting the tender, and also the decision-maker is the person who made an invitation to tender. In addition, the invitation to tender has to be announced publicly, and the person who made an invitation to tender agrees to perform the duty, which is to award the principal contract.

Therefore, the invitation to tender should be considered as aprize competition when such an invitation to tender is announced to the public. The person who made an invitation to tender undertakes to legally bound to every contestant that submit the qualified tender document on a specified period of time. The main condition is that only one contestant shall gain the prize by the method prescribed in such an invitation.

3. The foreign legal perspective of the tender process

3.1 The two-contract approach

The Common law system recognizes that the tender process, in some situations, creates the legal obligation. The unilateral contract in English law is introduced to protect the party's right to some degree that a person who submits the tender has the duty to not withdraw the tender before the specified time and date as prescribed in the invitation to

[17] Sanunkorn Sotthibandhu (n 4) 303.

tender[18]. From that point, the court also finds the solution to deal with the invitation to tender by imposing the implied duty for a person who made an invitation to tender for considering the tender fairly and equally.

The Canadian legal system takes a contractual obligation approach by establishing the process contract[19]. This approach is to create the precedent contract (Contract A) in which the obligation of both parties before the conclusion of the principal contract (Contract B). The condition of the Contract A depends on the condition prescribed in the invitation to tender. Usually, the tender procedure, evaluation method, submission date and time, bid guarantee, indemnity clause, and other conditions will be contained in the invitation to tender. New Zealand and Australia's legal system also apply the two-contract analysis to the tender case in which the consideration doctrine in particular.

It could be concluded that the first factor to consider the tender process contract is whether the tender documents conform with the invitation to tender. After the first criteria pass, then, the court will consider the condition of the tender process. For example, the evaluation process, the requirement for submitting the bid deposit, the correspondence between the tenderer and the tenderer regarding the evaluation criteria, and the bidding process's complexity[20]. The purpose of those mentioned factors is to consider whether the tender process has the intensity for binding both owner and tenderer or not. If so, then, the process contract is established with both parties' duty to oblige the condition set in the invitation to tender. if there is a breach of the process contract, both parties can claim damages based on the process contract.

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[18] *Harvela Investments Ltd v. Royal Trust Company of Canada (CI) Ltd* [1986] AC207 and *Blackpool and Flyde Aero Club v. Blackpool Borough Council* [1990] 1 WLR 1195

[19] *Ontario v. Ron Engineering & Construction (Eastern) Ltd* (1997) 146 ALR 1 (FCAust) and *Martel building Ltd. v. Canada*, 2000 SCC 60, [2000] 2 SCR 860

[20] Ronald W Craig, 'Controversial Aspects of Commonwealth Construction and Engineering Procurement Law' (DPhil, Loughborough University 2000) 218.

3.2 The pre-contractual liability

The concept of *culpa in contrahendo* is based on the duty of care between parties before they entered the contract. Before the reformation of Burgerliches Gesetzbuch (BGB) in 2002, this duty is considered an implied duty between parties[21]. Such an implied duty is based on the ground of the good faith principle. To clarify, the duty of care is about the duty to protect other parties' rights and interests before the conclusion of the contract. If one fails to perform the duty, such as the disclosure of the essential information that affects the contract, such a party is liable to other parties. This duty of care is now prescribed in section 311(2), which refers to section 241(2).

The German legal system recognizes the concept of negotiation that both parties may end the relationship any time before the conclusion of the contract, which may result from the change of scenario such as the change of cost, profit. However, such freedom will be restricted if one of the party convince another party that the contract will be concluded or one of the party fails to inform some situation that might affect to the conclusion of the contract to another party. Therefore, it breaches the duty to break off the negotiation[22].

In the author's view, it could be explained that the negotiation process between a person who made an invitation to tender and a successful tender is protected by the duty of care by section 311 (2) and 241(2). Interestingly, the application of section 241(2) may be interpreted in the broad sense as it prescribed that the obligation depends on the content, which means that the obligation between the person who made an invitation to tender and the person who submit the conformed tender is depended on the condition prescribed in the invitation to tender as the

[21] Xiao-Yang Li, 'The Legal Status of Pre-Contractual Liability: Contrasting Response from German and English Law' (2017) 12 NTU L Rev 127, 143-144.

[22] Hein Kotz, *European Contract Law* (Gill Mertens and Tony Weird trs, 2nd edn, OUP 2017) 37.

section 311(2) prescribed that the duty of care come to existence by the initiation of a contract[23].

Besides, the submission of tender documents is considered the beginning of the pre-contractual obligation between the person who made an invitation to tender and the person who submitted the tender[24].

The compensation for breaching section 241(2) is prescribed in section 280(1), which grants the damages for the damage that comes from such breach of duty. Moreover, if the requirement in section 280(1) is satisfied, the party may also claim the damages due to performance if it can be seen that such duty of performance cannot be fulfilled.

3.4 Promise approach

Apart from the *culpa in contrahendo* principle, there is the case that the court applies the promise principle to the prize competition, which has an element as same as the invitation to tender[25] as it is the prize competition. The fact for this case[26] is that the defendant made an architectural competition with the DM 22,000 prize for the winner. Two qualified contestants submit the product on time. However, the defendant error rejects the contestant on the ground that he submit lately. It turns out that the court decided that there is a contractual duty, according to section 661 of BGB. Therefore, the defendant breaches the duty to perform competition impartially.

The promise principle, under Scots law, itself can be considered as the unilateral obligation. This unilateral obligation is recognized in Scots law, and it is enforceable, which differs from English law. A promise creates an obligation to the promisor to perform what he undertakes. Failures to do so,

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[23] J Cartwright and M Hesselink (eds) *Precontractual Liability in European Private Law* (Cambridge University Press 2009) 289.

[24] BGH [1998] NJW 3636 at 3636 citation from Axel-Volkmar Jaeger and Götz-Sebastian Hök, *FIDIC - A Guide for Practitioners* (Springer-Verlag Berlin Heidelberg 2010) 96.

[25] Hein Kotz (n 22) 35.

[26] BGH 23 Sept. 1982, [1983] NJW 442.

the promisor will be liable and may be sued for enforceability of the obligation from what he promised.[27]

The Scots law recognizes the tender process's legal characterization into two types, depending on the condition prescribed in the invitation to tender. One is an offer, and another is a promise. However, the result from the contract approach or the unilateral obligation approach produces no different outcome. Also, the unilateral obligation concept does not face the theoretical problem like an English law that applies the unilateral contract. The damages also can be claimed on the ground of breaches of contract or promise.

4. The analysis of a suitable approach for Thai law

4.1 Two-contract approach

When observing the two-contract approach as introduced in the Canadian case, this approach is to create Contract A to set the obligation between the owner and the successful tenderer before the conclusion of Contract B. So the proposal is that the invitation to tender may constitute the process contract depending on the complexity of the tender process.

The question is whether the actual tender process contract can be established under Thai law or not. When considering the offer and acceptance approach, the invitation to tender contains the conditions that both owners and tenderers have to follow. Therefore, it is certain and precise enough. In the author's opinion, the invitation to tender is the offer made to the public, and the tender process contract should be established when submission of tender documents and binds to every candidate that submit the qualified bid. The obligation between the parties is to follow the conditions in the invitation to tender. Both parties of the tender process contract must oblige with the condition prescribed in the invitation to

[27] David M Walker, *The law of Contracts and related obligations in Scotland* (2nd edn, Butterworths 1985) 24-25.

tender. If the owner breaches of such duty, therefore, the person who submits the tender should claim the damages by the general obligation of law.

The next question does the obligation to enter the principal contract is existed or not. As mentioned, the Thai court does not mention the duty to enter the principal contract in the process contract. Tingsabadh and Sotthibandhu believe that both parties cannot force each other to conclude the contract. In the author's opinion, the nature of the tender process is also to select a suitable candidate in which the qualification is prescribed in the invitation to tender; therefore, the essential factor for the whole tendering process is the party's qualification. Thus, the specific performance for entering the contract cannot be enforced. The only option for both parties is to receive compensation for the loss.

The duty to enter the principal contract did not exist because the principal contract did not exist according to section 366 paragraph 2, and that is why the court also struggles to grant the damages to the parties when it appears that there is no contractual obligation between the parties[28]. Besides, it is a remarkable aspect to consider if the court can force the parties to enter the principal contract by the ground of the process contract while the parties refuse signing the contract. That decision shall interrupt section 366 paragraph 2 as both parties already declare the intention to make a contract in written form. The enforceability of the process contract to sign the contract will nullify both parties' intention that the parties have to enter the contract in the written form.

In some cases, the court further analyzes that if there is any action according to the contract, such as the land handover without the signing of the principal contract. The court interprets that the party deems to agree to omit the condition to signing the contract in a certain period because there

[28] Nattiya Tontrakulwanit, Panha Thangkotmai Reung Nhikornsanya [Legal Problems of Precontractual obligation] (Masters of Law Degree Thesis, Chulalongkorn University 2018) 164 (นัฐติยา ต้นตระกูลวาณิชย์ ,ปัญหาทางกฎหมายเรื่องหนี้ก่อนสัญญา) (วิทยานิพนธ์มหาบัณฑิต คณะนิติศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย 2561)) 164.

is a specific performance to hand the areas to be protected by other parties. The court explained that other damages could be claimed (if any)[29]. It is quite controversial because that appears the principal contract is already concluded without mentioned the process contract.

4.2 Prize competition

The concept of unilateral obligation, observing from the Scots law, is that only the promisor binds himself solely to perform what he undertakes. Therefore, the prize competition binds only the owner in the condition to award the contract to the tenderer who passing the condition set in the invitation to tender.

One of the benefits for application of the prize competition in the tender process is to grant the legal protection in the case where the person who is the winner of the tenderer wishes to claim the damages for the breaching of the condition as prescribed in the invitation to tender especially in the case where there is a cancellation of tender process at the time when it appears that the contestant is the winner.

Apart from that, the successful tenderer may claim the damages when there is a breach of the condition of the invitation to tender by the person who made an invitation to tender. Moreover, the court may apply to grant the damages to compensate when the owner denied signing the contract without any proper reason.

If the successful tenderer denied to sign the contract, the owner still recovered the loss from forfeiting the bid guarantee and also claim the damages according to the indemnity clause. Moreover, the owner can ask the second tenderer to enter the principal contract. Therefore, the promise principle balances the right and the duty between owner and tenderer more than two contract approach.

[29] The Decision of the Thai Supreme Court no. 6828/2557 (2014 A.D.)

4.3 Pre-contractual liability

Another approach that is worth considering for applying to the tender process is the *culpa contrahendo* or the pre-contractual liability. There is no *culpa in contrahendo* directly prescribed in the Thai legal system; it is the presumption that the Thai legal system did not recognize such a doctrine. the *culpa in contrahendo* can be used in Thai law in the form of the general principle of law. While the good faith principle did not create the obligation, however, it can apply to the case in order to be a tool for reviewing whether the parties exercise his right in good faith or not. Another way is to amend the Civil and Commercial Code to codify the concept of *culpa in contrahendo*.

If the court applies the *culpa in contrahendo* principles to the case. This application would generate a reasonable outcome as the submission of tender creates the duty of care to all the parties. The court, then, has the power to observe the circumstance in order to protect the interest of the parties. However, as mentioned earlier regarding the acknowledgment of such principle, the court may find the hardship to apply section 5 to the tender process because if the court confirms that there is no tender process contract between the parties, as such, how would the court apply section 5 to the case when there is no legal ground. However, if the court perspective changes to acknowledge the tender process contract or the prize competition according to the author's proposal. It would generate a better result.

5. Conclusion

To conclude, the two contract approach, the prize competition approach and *culpa in contrahendo* approach has the advantage and disadvantage depending on each scenario. The two contract approach established the firm contractual relationship between the owner and the tenderer but faced problems regarding the formation of a contract and the duty to enter the contract. The prize competition generates a better outcome in the circumstance that the owner denied signing the contract as

the duty to sign the contract can enforceable on the ground of prize competition. The *culpa in contrahendo* covers the case where there are breaches of the duty of care, which including the scenario where the owner acts in bad faith. However, such a concept still faces the main problem regarding the acknowledgment of such a principle in the Thai legal system because this concept did not prescribe in the statute law.

When compared with the criteria specified above, the prize competition still is the preferable approach because it does not face the theoretical problem regarding the offer and acceptance approach and duty to enter the contract. At the same time, it is arguable that the court has no case that is decided in the area of prize competition to the tender process while the court already acknowledges the tender process contract. This reason is sound; however, when considering the damages concept and section 366 paragraph 2, the court still finds the hardship to consider the tender process contract as to be the ground for claiming the damages, especially the damages relating to the duty to enter the contract. The suggestion to amend the CCC by adding the concept of *culpa in contrahendo* is quite interesting as it is the direct concept dealing with the pre-contractual phase. The author is not against that suggestion; however, it is more proper to apply the specific law that governs this case, which is the prize competition or the two-contracts approach rather than the general principle of law, which in accordance with the Thai legal jurisprudence.

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ALTERNATIVE CHOICE OF ORGAN DONATION IN THAILAND: A STUDY OF OPT-OUT AND MANDATED CHOICE SYSTEMS*

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Abstract

In today's societies, there is a continuing increase in the number of people who suffer from various ailments. More and more people are in need of organ transplantation, which provides the opportunity to save lives, increase life expectancy, and improve the quality of the recipients' lives. However, the major obstacle to organ transplantation is that there is a shortage of organ donors. With organ donation, an organ donor, alive or dead, allows for the transplant of their organ to another person. With regard to organ donation, Thailand uses a voluntary system or so-called "opt-in" system that relies on the express consent of the donor to donate an organ. No specific law deals specifically with organ donation, but the basic principles are provided by the Medical Council and the Red Cross. The problem of shortages of organ donation finds its roots in religion, culture, and emotions. The author presents herein various legal frameworks for organ donation in the United States of America, Singapore, France and regulations and theories related to the opt-in, opt-out, and mandated

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choice systems to solve organ deficiency problems and increase organ donor rates in these countries.

Keywords: Organ Donation, Opt-Out, Mandated Choice, Organ Transplantation

1. Introduction

The concept of replacing a part of the body for treatment has been around for a millennia[1]. The development of organ transplantation for treatment has been rapidly growing and driving more demand for organ transplants. In today's societies, there is a continuing increase in the number of people who suffer from various ailments. Organ transplantation is the best treatment for patients who are suffering from organ failure. Most of the patients suffering from organ failure tend to sit on the organ's waiting list for a long period. Delays may lead to the death of patients in waiting. Also, organ transplantation provides the opportunity to save lives and improve the quality of the recipients' lives[2]. However, an important fact of organ transplantation is the availability of potential donors. In recent years, the major obstacle to organ donation is the organ shortage crisis. As a result, the demands of patients who need organ transplants have seen a major increase. Even when medical technology has increasingly advanced, but the number of organ donations is unsatisfactory.

As for Thailand, no specific laws deal specifically with organ donation, but the basic principles are laid down by the Medical Council and the Red Cross[3]. The voluntary system (opt-in) that Thailand is currently using is based on a voluntary system or a so-called "opt-in system".

Hence, the organ donation system relies on donor's expression of consent in advance of their death. This system results in a problem of shortage in organ donation. Even though many people wish to become

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[1] Clyde F Barker and James F Markmann, 'Historical Overview of Transplantation' (2013) < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684003/> accessed 20 November 2019.

[2] Kidney Health, 'Organ and Tissue Donation and Transplantation Fact sheet' (*Kidney Health*, July 2017) <https://kidney.org.au/uploads/resources/organ-and-tissue-donation-and-transplantaion-fact-sheet.pdf> accessed 10 November 2019.

[3] Sukit Thatsanasunthornwong, 'Organs Transplantation and Organs Donation in Thailand' (*OK Nation,* 4 September 2010) <http://oknation.nationtv.tv/blog/sukit/2010/09/04/entry-3> accessed 30 June 2020.

donors, they often forget or refrain from registering because of their lack of knowledge about organ donation and/or they still have not made a clear decision yet. This is one of the reasons why the number of organ donors is quite low and cannot keep up with the demand.

2. The basics of organ donation

Organ donation is the process whereby an organ donor, alive or dead, has given permission to transplant their organ to another person. The removal and the placing of the organ into someone else's body to treat the recipient who suffers from a damaged organ is called transplantation. The process of organ transplantation requires explicit consent to donate, whether from the relatives or from people who have expressed their consent prior to their death. The system of donating is divided into three systems. The system is "opt-in" or express consent and "opt-out" or presumed consent and mandated choice is a situation required for obtaining consent.

3. The shortage of organ donation in Thailand

Approximately 45,648 potential donors have registered in Thailand, but they have been only 122 donations, and there remain 5,840 patients registered on the organ waiting list and only 268 transplant recipients listed from the 2019 Annual Report of an organ donation center in Thailand[4]. Most Thai people still believe that it would be a problem to be born with incomplete organs in their next life and that organ donation will cause suffering to the deceased donor. Religious beliefs in this regard are very important to this day in Thai society. As such, the problem is not merely the low rate of organ donors, but the overall rate of organ transplants partly because many people decide not to register for donation. The results

[4] 'Raignarn Prachumpee 2562 Suun Rap Bawrih jaak Awaiwa Saphakachat Thai [the 2019 Annual Report of organ donation center in Thailand] (รายงานประจำปี 2562 ศูนย์รับบริจาคอวัยวะสภากาชาดไทย)' (*Organ Donate*, 2018) <https://www.organdonate.in.th/assets/files/odc2562.pdf> accessed 5 August 2020..

showed that the opt-in system cannot solve the problem without an effective law to boot.

4. Issues concerning organ donation legislation in Thailand

The main issue with the legislation determining organ donation and transplantation principles is not easily available and there currently exists no law passed by the Parliament that deals with the subject. There is thus a gap in the law for this important topic. Additionally, the current system for the enforcement mechanism is weak. There exist regulations on organ donations under medical ethics rules, the Thai red cross and organ donation centers. Yet these rules and regulations are fragmented. Also, the medical ethics rules still lack clarity regarding the status of the donor, heir, or relative, also the legal obligation of physicians. The medical council regulations did not specify the status of the donor and the rights of the relative clear enough. Moreover, the medical council regulations provide doctors must ask for consent from a relative before removing an organ even if that person has made an intention with the organ donation center according to article 53(3). Thus, the right of the donor's relative may be conflicting with the intent of the donor.

5. Legal frameworks in other countries

Many countries amended their law to respond adequately to the increasing demand for organ transplantation and the problem of the supply of organ donors.

In Singapore, organ donation is organized into two systems: opt-in and opt-out[5]. The opt-in is covered by the Medical (Therapy education and research) Act (MTERA). The Opt-out is covered by the Human Organ Transplant Act (HOTA). The HOTA provides the hard opt-out system that

[5] 'What is HOTA all about?' (*Singapore Government Agency Website*, 21 August 2013) <https://www.gov.sg/article/what-is-hota-all-about> accessed 1 October 2020.

allows only for the removal of kidneys, livers, hearts, and corneas from all citizens and permanent residents who have died in Singapore. This method gives utmost importance to the donor's intent.

In the State of New York, organ donation is governed by the system of Mandated choice[6]. The Mandated choice is a system of voluntary consent, but this system differs from a presumed consent policy. Under mandated choice, all citizens would be required to decide to be donors or non-donors at the mandated time. The state set up the law for the operation situation or scenario in which required people to making-decision in advance. For example, In New York, the state will ask for an organ donation as one of a process during renewing driver's license. Even though, people might hesitate to decide to donate their organs in the time of life. This method can see people's real intentions to donate an organ.

In France, the system for organ donation is opt-out presumed consent. All adults in France are presumed to be organ donors except when they have registered to object to being a donor or if they are under someone else's guardianship[7]. The opt-out in France is a soft opt-out. Thus, the doctors in France will always be asking consent with the family in practice before the surgery and they receive a refusal in about one-third of the cases. The family felt pressured are less willing to donate. Even in France where the opt-out system is used, low organ donation rates remain low due to a relatively high rate of refusal by the relatives.

6. Conclusion

To approach the topic of organ transplantation, Thailand should enact specific laws concerning organ donation and organ transplantation that prescribes rules and procedures for physicians in the same law. The

[6] Britta Martinez, 'Uniform Anatomical Gift Act (1968)' (*Embryo*, 5 August 2013) <https://embryo.asu.edu/pages/uniform-anatomical-gift-act-1968> accessed 21 July 2020.

[7] 'The French legal system' (*Ministry of Justice*, November2012) <http://www.justice.gouv.fr/art_pix/french_legal_system.pdf> accessed 23 December 2019.

opt-in system currently used is not effective with regard to the number of donations needed. New rules should also set accurately the duties and responsibilities of physicians. Therefore, the alternative of implementation to solve organ shortage problems should enact in a mixed system with opt-in and mandated choice to eincrease organ donation as follows:

6.1 Opt-in for all organs

To achieve the improvement of the number of organ donors, the author suggests that Thailand should adopt the Singapore approach to the opt-in system for all organs. There should be a specific law to govern organ donation systematically and set the standards, qualifications, and obligations of the donor. It should define the status of the donor as well.

6.2 Mandated choice for only kidney

Also, the author suggests that there should be an adoption of mandated choice that applies only to kidneys. In Thailand, the most commonly identified causes of renal disease are kidney transplants 6,125 cases were available total waitlist organs from a total 6,417 of organ recipients of the Thai transplant society report on December 31, 2019[8]. Also, patients with kidney disease or kidney failure have been challenged by expensive medications. To improve the efficiency of their health care, the transplant is the best treatment. Thus, mandated choice models that select only kidney may provide a possible method of increasing donation. New York creates a mandated choice to increase donors through the renewal of driver's licenses. However, the author thought it remains difficult to recognize the intention of people who do not drive. In this regard, the author suggests that Identification card (ID card) renewal should recognize

[8] Thai Transplantation Society, 'Annual Report 2019 Organ Transplantation in Thailand' (*Thai Transplantation Society*, 2019) <http://www.transplantthai.org/upload/editor/file/Registrybook-62Final.pdf> accessed 6 November 2020.

the intention of people that decided to donate an organ or refuse at that time. Therefore, an approach such as mandated choice may be part of a possible solution to address the shortage of organs for transplantations.

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CONSTITUTIONALITY OF STATUTORY PRESUMPTIONS WITH RESPECT TO THE CRIMINAL OFFENCE OF INSIDER TRADING*

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Abstract

In 2016, the Securities and Exchange Act (No. 5) B.E. 2559 ("SEA 2016") has introduced the statutory presumptions of knowledge or possession of inside information of certain groups of related persons in Section 243 and Section 244 with respect to the criminal offence of insider trading to eliminate obstacles in law enforcement created by the high standard of proof in criminal cases. In Thailand, the issue regarding the validity of the provisions which contain statutory presumptions in criminal cases like Section 243 and Section 244 has been a topic of discussion among legal scholars as it can possibly lead to the unconstitutionality of such provisions due to violation of the fundamental right to be presumed innocent as recognized in the Constitution of the Kingdom of Thailand as the supreme law of the state.

In order to analyze the constitutionality of the statutory presumptions contained in Section 243 and Section 244 of SEA 2016, this article applies documentary research method under the 3 different

* This article is summarised and rearranged from the thesis "Constitutionality of Statutory Presumptions with Respect to the Criminal Offence of Insider Trading", Faculty of Law, Thammasat University, 2019.

approaches generally used to assess the constitutionality of statutory presumptions; (1) Pattern Approach; (2) Rational Connection Test Approach; and (3) Principle of Proportionality Test Approach.

According to the result of the analysis, the author found that the statutory presumptions contained in all subsections of Section 243 and Section 244 are constitutional under the Pattern Approach. However, the analysis conducted according to the Rational Connection Test Approach and the Principle of Proportionality Test Approach resulted in the author's finding that Section 243 (5) is unconstitutional due to its lack of rational connection between the basic fact and the presumed fact and its failure to achieve the goal pursued under the suitability test.

Keywords: Insider Trading, Statutory Presumption, Presumption of Innocence, Constitutionality

1. Introduction

Insider trading is an act of buying or selling securities by a person who has access to material information about the company's operation when such information has not been announced to the public. In many countries, this kind of trading practice is considered an illegal act because it is seen as unfair to other investors who do not know or have access to such information as the investors with inside information have more potential to make more profit than the other general investors in the market.

In Thailand, the measure against insider trading was put in place for the first time in 1984 under Section 42 Quintus of the Stock Exchange of Thailand Act B.E. 2527 (No. 2) ("SEA 1984") which was largely influenced by Rule 10 b-5 promulgated by virtue of Section 10 (b) of the Securities and Exchange Act of 1934 and Section 16 (b) of the Securities Exchange Act of 1934 of the United States. Section 42 Quintus was subsequently replaced by Section 241 of the Securities and Exchange Act B.E. 2535 ("SEA 1992").

Recently in 2016, the SEA 2016 which came into effect on 12 December 2016 was enacted with aims to ensure creditability of the Stock Exchange of Thailand and confidence of investors as well as to eliminate certain limitations under SEA 1992 which had prevented efficient enforcement of criminal penalties against offenders of securities-related offences and also to introduce civil penalty which can be enforced against offenders in place of criminal penalties in order to ensure the efficiency of enforcement and to provide more protection for investors[1].

Under SEA 2016, there have been major changes in the provisions governing the prevention of unfair securities trading practices in Thailand, one of which is insider trading offence. The provisions governing unfair trading practices under the SEA 2016 were influenced by the Derivatives Act B.E. 2546 and securities law of other countries such as the United Kingdom, Australia, Singapore, Malaysia and the Market Abuse Directive of the

[1] Securities and Exchange Act (No. 5) B.E. 2559 (2016).

European Union as well as experiences of the Office of Securities and Exchange Commission[2].

One of the major changes introduced by SEA 2016 is the statutory presumptions in relation to market misconducts for the purpose of easing the burden of proof of the authorities and eliminate limitations in criminal proceedings in order to improve the efficiency of law enforcement and to ensure successful criminal prosecution[3].

For insider trading offence, Section 243 and Section 244 of SEA 2016 provide two lists of persons who are presumed to have knowledge or possession of inside information for the first time since 1984.

2. Statutory Presumptions of Knowledge or Possession of Inside Information

According to Section 243 of SEA 2016, 5 groups of persons are presumed to have knowledge or possession of inside information as a result of certain relationships or connections which they have with securities issuing companies by virtue of their performance of duties in both private and public sectors which allow them to obtain inside information (Section 243 (1), (2), (3), (4)), or, due to the reason of being juristic person operating business that is under other presumed persons' control (Section 243 (5)).

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[2] Fiscal Policy Office, Bantuek Khorkhwam Rueang Rang Phraratchabanyat Lhaksap Lae Talad Lhaksap (Chabab Ti ...) Phor.Sor... [Memorandum on Securities and Exchange Bill (No...) B.E...(2014)] 4 (สำนักงานเศรษฐกิจการคลัง สำนักนโยบายการออม, บันทึกข้อความ เรื่อง ร่างพระราชบัญญัติหลักทรัพย์และตลาดหลักทรัพย์ (ฉบับที่ ...) พ.ศ. ...) 4.

[3] Secretariat of the Senate, Ekkasan Prakop Kan Pitcharana Rang Phraratchabanyat Lhaksap Lae Talad Lhaksap (Chabab Ti ...) Phor.Sor. ... (Khanarattamontree Pen Phusanoe) [Documents in Support of Consideration in relation to the Securities and Exchange Bill (No...) B.E.... (Proposed by the Cabinet)] (2016) 10 (สภานิติบัญญัติแห่งชาติ, เอกสารประกอบการพิจารณา ร่างพระราชบัญญัติหลักทรัพย์และตลาดหลักทรัพย์ (ฉบับที่ ...) พ.ศ.... (คณะรัฐมนตรี เป็นผู้เสนอ) 10.

Section 243 of SEA 2016 provides that:

It shall be presumed that the following persons have known or possessed the inside information under Section 242:

(1) director, executive or controlling person of a securities issuing company;

(2) employee or staff of a securities issuing company who holds a position, or is in the line of work, responsible for or capable of accessing inside information;

(3) any person who is able to know inside information by performing duties as auditor, financial advisor, legal advisor, asset appraiser or any other person whose duties are related to inside information, including employees, staffs or colleagues of the aforesaid persons who hold a position or is in the line of work involved in the performance of duties related to such inside information;

(4) director, sub-committee member, representative of a juristic person, agent, staff, employee, advisor or operator in a governmental agency, the SEC Office, the Stock Exchange, the over-the-counter center or the Derivatives Exchange, who is in the position or the condition that can access inside information through performance of duties;

(5) juristic person whose business is under control of the persons under (1) (2) (3) or (4).

Moreover, under Section 244, the presumption of knowledge and possession of inside information is expanded to cover the second group of persons who are shareholders holding more than 5 percent shares (Section 244 (1)), a corporate insider of group companies (Section 244 (2)), and close relatives of persons presumed to have knowledge or possession of inside information under Section 243 (Section 244 (3), (4), (5)) if they trade in a manner different from their normal practice.

Section 244 of SEA 2016 provides that:

It shall be presumed that the following persons, who have traded securities or entered into a derivatives contract in a different manner from their normal practice, have known or possessed the inside information under Section 242:

(1) holder of securities exceeding five percent of the securities issuing company's total securities sold, including the securities held by spouse or cohabiting couple and minor children of the securities holder;

(2) director, executive, controlling person, employee, or employee of business in the group of the securities issuing company, who holds a position or the line of work responsible for or capable of accessing inside information;

(3) parent, descendant, child adopter or adopted child of the persons under Section 243;

(4) sibling of the same blood parents or sibling of the same blood father or mother of the persons under Section 243;

(5) spouse or cohabiting couple of the persons under 243 or the persons under (3) or (4).

Business in the group of a securities issuing company under (2) means parent company, subsidiary or affiliate of the securities issuing company in accordance with the rules as specified in the notification of the SEC.

3. Principle of Presumption of Innocence

In the context of criminal law, the issues regarding statutory presumptions have been a topic of controversial discussion for a long time. Even though some legal scholars were of the opinion that presumptions in criminal cases are necessary as they would be beneficial for the purpose of maintaining public order especially for the criminal offences which are

difficult to prove[4], some viewed that statutory presumptions in criminal case violate the presumption of innocence principle[5].

The presumption of innocence is the constitutional principle recognized in Section 29 Paragraph Two of the Constitution of the Kingdom of Thailand B.E. 2560 which provides that[6]:

"Suspect or defendant in a criminal case shall be presumed innocent, and before the passing of a final judgment convicting a person of having committed an offence, such person shall not be treated as a convict"

Section 29 Paragraph Two of the Constitution is the provision that aims at protecting the rights of the accused or defendants in criminal proceedings.

Under the principle of presumption of innocence, the accused or defendant is presumed to be innocent until his or her guilt has been proven by a final judgment[7]. This principle is founded on the human rights principle as appeared in Article 11 of the Universal Declaration of Human Rights.

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[4] Kraiphon Aranyarat, Bhot Wikhroe Kham Phipaksa Phon Krathop Khong Kham Winitchai Sarn Rattathammanoon Tee 12/2555 Thor Kham Samar Nai Karn Sawaengha Phayan Lakthan Phue Pisood Khamphid Khong Jamloei Nai Khadee Arya [Effects of Decision of Constitutional Court No. 12/2555 on Ability to Gather Evidences to Prove Guilt of Defendants in Criminal Case] [2012] <http://public-law.net/publaw/view.aspx?id=1797> accessed on 16 October 2019 บทวิเคราะห์คำพิพากษา ผลกระทบของคำวินิจฉัยศาลรัฐธรรมนูญที่ 12/2555 ต่อความสามารถในการแสวงหาพยานหลักฐานเพื่อพิสูจน์ความผิดของจำเลยในคดีอาญา เข้าถึง 16 ตุลาคม 2562.

[5] Udom Rathamarit, Kham Athibai Kotmai Laksana Phayan Lakthan [Explanation on Law of Evidence (7th edn, Project for Promotion of Textbooks and Teaching Materials, Faculty of Law, Thammasat University 2019) 213 (อุดม รัฐอมฤต, คำอธิบายกฎหมายลักษณะพยานหลักฐาน (พิมพ์ครั้งที่ 7 โครงการตำราและเอกสารประกอบการสอน คณะนิติศาสตร์ มหาวิทยาลัยธรรมศาสตร์ 2562)) 213.

[6] Constitution of the Kingdom of Thailand B.E. 2560

[7] Constitutional Court Decision of No. 12/2555

4. Assessment of Constitutionality of Statutory Presumptions under the 3 Different Approaches

After having reviewed several decisions of the Constitutional Court of Thailand as well as opinions and articles regarding the approaches applied for considering the constitutionality of laws in Thailand, the author found that there are 3 relevant approaches which have been applied in the assessment of the constitutionality of statutory presumptions as follows:

4.1 Pattern Approach

According to the decisions of the Constitutional Court, the provisions which are in conflict with the presumption of innocence principle under the Constitution are the provisions which provide presumptions of guilt of certain persons based on his or her status without any proof of his or her action nor intention. Therefore, it can be summarized that the provision of law would be considered unconstitutional if it provides the status of the defendant as a basic fact and guilt of such a defendant as a presumed fact. This criterion of consideration established by the Constitutional Court is explained by several legal scholars as "Pattern Approach"[8].

According to the said precedent of the Constitutional Court of Thailand, the following rules can be inferred:

Pattern	Basic Fact	Presumed Fact	Constitutionality
Pattern 1	Status of Defendant	Guilt of Defendant	Unconstitutional
Pattern 2	Status of Defendant	Element of Crime	Constitutional
Pattern 3	Action of Defendant	Guilt of Defendant	Constitutional
Pattern 4	Action of Defendant	Element of Crime	Constitutional

[8] Khemchai Chutiwong, Kham Athibai Kotmai Laksana Phayan [Explanation on The Law of Evidence] (9th edn, Samnak Oprom Kotmai Ngae Netbanthittayasapha 2014) 122 (เข็มชัย ชุติวงศ์, คำอธิบายกฎหมายลักษณะพยาน (พิมพ์ครั้งที่ 9, สำนักอบรมศึกษากฎหมายแห่งเนติบัณฑิตยสภา, 2557)) 122.

After considering the elements of statutory presumptions contained in Section 243 and Section 244, the author found that the statutory presumptions contained in Section 243 fall into the scope of Pattern 2 and the statutory presumptions contained in Section 244 fall into the scope of Pattern 2 and Pattern 4.

4.2 Rational Connection Test Approach

In addition to the "Pattern Approach", several legal scholars also expressed their opinions that the Constitutional Court should look further into the substance contained in each statutory presumption to consider whether or not there is any reasonable connection between the basic fact and the presumed fact according to the Rational Connection Test Approach as established by the Supreme Court of the United States[9].

The constitutionality of statutory presumption under the Rational Connection Test Approach depends mainly on the connection between the basic fact and the presumed fact. Under this approach, the question of whether or not there is a rational connection between the basic fact and the presumed fact is asked[10].

Unlike the Pattern Approach, in order to answer such question, the substance of each statutory presumption will have to be analyzed according to the criteria set by the decisions of the US Supreme Court which explained that the rational connection between the presumed fact and the basic fact can only be established when common experiences suggest that the presumed fact is more likely than not to flow from the proved fact (basic fact) on which it is made to depend[11].

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[9] ibid.

[10] Jaran Phakdeethanakool, Kotmai Laksana Phayan Lakthan [Explanation of Law of Evidence] (14edn, The Institution of Legal Education of Thai Bar Association 2019) 194 (จรัญ ภักดีธนากุล, กฎหมายลักษณะพยานหลักฐาน (พิมพ์ครั้งที่ 14 สำนักอบรมศึกษากฎหมายแห่งเนติบัณฑิตยสภา 2561)) 194.

[11] *Leary v. United States* 396 U.S. 6 (1969) 8.

With respect to the statutory presumptions contained in Section 243 and Section 244, the constitutionality of these statutory presumptions under the Rational Connection Test Approach was analyzed according to the following criteria:

(1) If, considering the status of persons (basic fact), the knowledge or possession of inside information (presumed fact) is more likely than not to happen, the statutory presumptions contained in Section 243 or Section 244 will be held constitutional; and

(2) If, considering the status of persons (basic fact), the knowledge or possession of inside information (presumed fact) is not likely to happen, the statutory presumptions contained in Section 243 or Section 244 will be held unconstitutional.

As a result of the above explanation, the author found that the knowledge or possession of inside information of the issuing company is more likely than not to flow from the status of those persons who are directly connected to the issuing company and work in the position or condition which allows them to know or possess inside information.

4.3 Principle of Proportionality Test Approach

In addition to the "Pattern Approach" and the "Rational Connection Test Approach", the Principle of Proportionality is generally accepted in several countries as well as international courts as the basic principle for determining the validity of laws and government actions. In Thailand, the Principle of Proportionality is recognized in Section 26 of the Constitution of the Kingdom of Thailand B.E. 2560 which provides that the enactment of a law resulting in the restriction of rights or liberties of a person shall be in accordance with the principle of proportionality[12].

[12] Boonsri Meewong-Ukot, Khotmai Ratthathammanun [Constitutional Law] (3rd edn, Project for Promotion of Textbooks and Teaching Materials, Faculty of Law, Thammasat University 2009) 506 (บุญศรี มีวงศ์อุโฆษ, กฎหมายรัฐธรรมนูญ (พิมพ์ครั้งที่ 3, โครงการตำราและเอกสารประกอบการสอนคณะนิติศาสตร์ มหาวิทยาลัยธรรมศาสตร์ 2562)) 506.

The analysis of the constitutionality of statutory presumptions contained in Section 243 and Section 244 under the Principle of Proportionality Approach was divided into 3 parts according to the 3 elements of the principle of proportionality as follows:

4.3.1 Principle of Suitability

Under the principle of suitability, the question of whether the measure selected is capable of achieving the pursued legitimate objective[13] or in other words, whether the selected measure is rationally connected to the pursued objective is asked. The selected measure in issue will not be considered suitable if there is no rational connection between the selected measure and the pursued objective.

In order to consider whether the statutory presumptions contained in Section 243 and Section 244 are suitable, 2 factors are required to be considered as follows:

(1) Legitimate objective of Section 243 and Section 244;

The objective of Section 243 and Section 244 is to improve the efficiency of criminal prosecution against insider trading offence.

(2) Selected measure;

The measure selected in order to achieve the legitimate objective of improving the efficiency of criminal prosecution against insider trading offence is to lower the burden of proof on the part of the prosecutor by employing the statutory presumptions of knowledge or possession of inside information of certain groups of persons.

To answer the question of suitability, the author firstly took into consideration the result of the analysis conducted in the previous part under the Rational Connection Test. This is due to the reason that the lack

[13] Bunjerd Singkaneti, Lak Phunthan Kiawkap Sitthi Seriphap Lae Saksi Khwampen Manut [Fundamental Principle of Rights, Liberties and Human Dignity] (6th edn, Winyuchon 2019) 24, 30 (บรรเจิด สิงคะเนติ, หลักพื้นฐานเกี่ยวกับสิทธิเสรีภาพและศักดิ์ศรีความเป็นมนุษย์ (พิมพ์ครั้งที่6 วิญญูชน 2562)) 24, 30.

of a rational connection between basic facts and presumed facts indicates that such statutory presumption cannot contribute to the pursued goal which is to increase the efficiency of criminal prosecution of insider trading. Instead, the efficiency of criminal prosecution is rather decreased because criminal investigations are likely to be launched without reasonable suspicion.

As the analysis under the Rational Connection Test indicates that only the rational connection of the basic fact and the presumed fact Section 243 (5) cannot be established, only Section 243 (5) fails the suitability test in this step. For remaining statutory presumptions contained in Section 243 and Section 244 which have passed the Rational Connection Test, they would be considered suitable if they can contribute to the accomplishment of the pursued legitimate objectives.

Given the provision contained in Section 242, the prosecutor is required to prove the following external elements of insider trading offence if the statutory presumptions of knowledge or possession of inside information do not exist:

(1) Prohibited action

(2) Knowledge or possession of inside information

However, according to the law of evidence, the statutory presumptions can shift to the defendant the burden to prove the elements of a crime which are provided as presumed fact. This means that, as a result of the statutory presumptions contained in Section 243 and Section 244, the prosecutor does not have to prove the knowledge or possession of inside information of the offender which is one of the essential elements of inside trading offence provided in Section 242 of SEA 2016 and will be required to prove only the prohibited action of the offender. For the reason that burden of proof on the prosecutor part is lowered, the criminal prosecution taken against a person committing insider trading offence is likely to be more successful. Therefore, the legitimate objective being pursued that is the increase of efficiency in criminal proceedings can be accomplished by the selected measure.

4.3.2 Principle of Necessity

With respect to Section 243 and Section 244 of SEA 2016, the issue required to be considered in order to answer the question of necessity starts with the issue of whether or not there is another equally effective measure that can increase the efficiency of criminal proceedings against insider trading offence. Once and if such a measure can be identified, the next question is whether or not it is less harmful to the right to be presumed innocent of the defendant compared to the rebuttable presumption of knowledge or possession of inside information.

After having duly examined all possible alternatives within the scope of criminal law, the author has found other 2 potential alternatives which should be taken into consideration as follows:

1. Improvement of criminal proceedings

To increase the efficiency of criminal proceedings against insider trading offence, the government may choose to improve the process of investigation and fact-finding.

With respect to the "less restrictive" question, this choice undoubtedly creates less harm to the right to be presumed innocent than the statutory presumptions of knowledge and possession of inside information as it does not in any way create any burden on the part of the defendant. However, there is no guarantee regarding the effectiveness of this alternative due to the difficulty in proving the element of knowledge or possession of inside information and the issue of whether or not such difficulty which has prevented the successful criminal proceedings against insider trading offence can be overcome remains questionable.

Therefore, even though this alternative is less restrictive, it is not equally efficient compared to the statutory presumptions of knowledge or possession of inside information provided in Section 243 and Section 244.

2. Irrebuttable presumptions

To increase the efficiency of criminal proceedings, another type of statutory presumption i.e. irrebuttable presumption may be provided instead of a rebuttable presumption. In this case, the provision of Section

243 and Section 244 would provide that certain groups of persons are deemed (instead of "presumed") to have knowledge or possession of inside information. In the case of rebuttable presumptions, even though the prosecutor would not have to prove the element subject to the presumption at the beginning, it would still be required to bear the burden of proof if the defendant successfully challenges the presumed fact. However, in the case of the irrebuttable presumption, as the defendant would not have a chance to challenge the presumed fact, the prosecutor would have no further obligation to prove in the case that the defendant successfully challenged the presumed fact. As a result, the prosecution's burden of proof with respect to the knowledge or possession of inside information would not only be lowered but it would be entirely removed.

For the above reasons, as to the question of effectiveness, the irrebuttable presumption can definitely contribute to the pursued objective of increasing the effectiveness of criminal proceedings. However, this alternative would create more harm to the right of the persons subject to the rebuttable presumption according to the reasons explained above.

Based on the above analysis of the 2 alternatives available, it can be seen that there is no other measure which is equally effective and less restrictive. The author, therefore, concludes that the statutory presumptions contained in Section 243 and Section 244 of SEA 2016 pass the necessity test.

4.3.3 Principle of Proportionality Test in a Strict Sense

The answer to the question of whether the statutory presumptions contained in Section 243 and Section 244 are proportionate in a strict sense, the careful balancing of public interest which will be obtained and the right of individual being affected is required. Under this principle, the question of

whether a restriction is justified when comparing the benefit to the goal being pursued to the impact on rights[14].

As already explained in the foregoing assessment under the suitability test and the necessary test, the statutory presumptions contained in Section 243 and Section 244 were introduced in order to increase the efficiency of criminal proceedings against insider trading offence. Once the pursued objective is achieved, what will surely happen is less violation of insider trading law. This can increase the confidence of investors in the market and also indicates more fairness in trading practice in the stock market. As the stock exchange plays an important role in the country's economy as a source of fundraising to the business and a source of fund saving to the people, this will benefit the country's economy as a whole. With respect to the affected right of the individual, the author views that the persons subject to statutory presumptions contained in Section 243 and Section 244 are not left with no ground to challenge their presumed knowledge or possession of inside information given that such statutory presumptions are rebuttable. Moreover, they also have grounds to claim that even though they have knowledge or possession of inside information their actions fall within the scope of exceptions as provided in Section 242.

5. Conclusions and Recommendations

5.1 Constitutionality of Statutory Presumptions with Respect to Criminal Offence of Insider Trading

[14] Lasse Schuldt, 'Publishing Secrets: A Case Study on the Balancing of Press Freedom and Public Interests in European Human Rights Jurisprudence' (2019) 48(4) Thammasat Law Journal 760, 769.

5.1.1 Conclusion

According to the analysis conducted under the Pattern Approach, the Rational Connection Test Approach, the Principle of Proportionality Test Approach, the constitutionality of the statutory presumptions contained in Section 243 and Section 244 can be summarized as follows:

(1) Section 243

Approach / Section	Pattern Approach	Rational Connection Approach	Principle of Proportionality
Section 243 (1)	Constitutional	Constitutional	Constitutional
Section 243 (2)	Constitutional	Constitutional	Constitutional
Section 243 (3)	Constitutional	Constitutional	Constitutional
Section 243 (4)	Constitutional	Constitutional	Constitutional
Section 243 (5)	Constitutional	Unconstitutional	Unconstitutional

(2) Section 244

Approach / Section	Pattern Approach	Rational Connection Approach	Principle of Proportionality
Section 244 (1)	Constitutional	Constitutional	Constitutional
Section 244 (2)	Constitutional	Constitutional	Constitutional
Section 244 (3)	Constitutional	Constitutional	Constitutional
Section 244 (4)	Constitutional	Constitutional	Constitutional
Section 244 (5)	Constitutional	Constitutional	Constitutional

According to the result of analysis, only Section 243 (5) is considered unconstitutional under the Rational Connection Test Approach and the Principle of Proportionality Test due to its lack of rational connection between the basic fact and the presumed fact which indicates that Section 243 (5) fails the Rational Connection Test Approach and the Principle of Proportionality Test Approach.

5.1.2 Recommendation

Following the conclusion explained in Item 5.1.1 above, it is recommended that the unconstitutional statutory presumptions of knowledge or possession of inside information with respect to the criminal offence of insider trading contained in Section 243 (5) be removed from Section 243

However, given the fact that their business is under the control of the connected persons, the author views that the chance that the juristic persons subject to Section 243 (5) may have known or possessed inside information of the issuing company is higher than other general persons. However, such fact alone cannot establish a rational connection between the basic fact and the presumed fact unless there is another factor which can increase the possibility of knowledge or possession of inside information. For the same reason used to support the rational connection between the basic fact and the presumed fact of the statutory presumptions contained in Section 244, the author views that the most possible explanation which can establish the rational connection is Unusual Trading Behavior.

For that reason, it is recommended that the provision contained in Section 243 (5) should be moved to Section 244. As a result, there would be a rational connection between the knowledge or possession of inside information and the Unusual Trading Behavior of the person who has a

higher chance to know or possess inside information than other general persons.

5.2 Advancing the Assessment of the Constitutionality of Statutory Presumptions

5.2.1 Conclusion

The analysis conducted separately under the 3 different approaches may seem to be different given the fact that the factors which are taken into consideration in an attempt to determine the constitutionality of law vary according to the criteria required by the respective approach.

However, after taking all questions under the 3 different approaches into consideration, the author views that all issues which have been analyzed under the Pattern Approach and the Rational Connection Test are actually incorporated as part of the assessment under the Principle of Proportionality Test. The said conclusion can be explained as follows:

(1) Pattern Approach

According to the precedent of the Constitutional Court of Thailand, the statutory presumption which fails the Pattern Approach is the presumption under which the defendant's guilt is presumed without any proof of the defendant's action or intention. The same result would be derived from the assessment of the statutory presumption under the necessary test of the Principle of Proportionality Approach as the presumption of guilt would be considered to be more restrictive than other available measures, for example, presumptions of a certain element of a crime even when they can also contribute to the same legitimate objective being pursued.

(2) Rational Connection Test

According to the Rational Connection Test Approach, the statutory presumption which fails the Rational Connection Test is the presumption under which there is no rational connection between the basic fact and the presumed fact. The same result would be derived from the assessment of the constitutionality of the said statutory presumption under the first step test of the Principle of Proportionality Approach due to the reason that the lack of rational connection between the selected measure and the pursued objective means that such statutory presumption cannot contribute to the pursued objective and the statutory presumptions in question would then fail the test of suitability.

5.2.2 Recommendation

According to the above conclusion, it can be seen that, by following the 3-step test of the Principle of Proportionality Approach alone, the Constitutional Court will have an opportunity to look into and analyze every aspect of the statutory presumptions and render relevant decisions in a more systematic manner. Moreover, the extent to which the fundamental right to be presumed innocence is limited as created by the statutory presumption will remain within the scope of rationality, suitability, necessity and proportionality which are the essential factors that should not be compromised and taken for granted.

For these reasons, the separate assessment under the Pattern Approach and the Rational Connection Test approach is no longer necessary and it is therefore suggested that the Principle of Proportionality Test should be applied in the assessment of the Constitutional Court of Thailand to determine the constitutionality of the statutory presumptions.

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LEGAL PROBLEMS CONCERNING NOMINEE ARRANGEMENTS IN RELATION TO FOREIGN BUSINESS UNDER THAI LAWS*

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Abstract

This article explores the problems of nominee arrangements under the Foreign Business Act B.E. 2542 (hereinafter the "**FBA**"), which is caused by the impractical definition of "foreigners" under Section 4 of the FBA, and the unclear criteria relating to what constitutes a "nominee arrangement", which is prohibited under the relevant laws.

Nominee arrangements are a major problem for foreign business laws in Thailand, as they allow foreigners to circumvent laws which aim to protect the economic interests of Thailand against foreign ownership and control, and protect the interests of Thai businesses in sensitive sectors in which Thai businesses may not yet be ready to compete with multinational corporations looking to expand the scope of their business to Thailand.[1]

Despite the laws being effective for over 40 years, the nominee arrangement problem remains a prominent and long standing issue in

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* This article is summarised and rearranged from the thesis "Legal Problems Concerning Nominee Arrangements in Relation to Foreign Business under Thai Laws" Faculty of Law, Thammasat University, 2019.

[1] Sakon Harnsuthivarint, 'Nominee Tue Hoon Tan Khon Tang Dao [Nominee Holding Shares for Foreigners]' (*Bangkokbiznews,* 8 March 2016) (สกล หาญสุทธิวาริน์ทร์, '"นอมินี" ถือหุ้นแทนคนต่างด้าว' (*กรุงเทพธุรกิจ*, 8 มีนาคม 2559)) <https://www.bangkokbiznews.com/blog/detail/637132> accessed 24 September 2019.

Thailand, and thus, it is essential to find suitable and practical solutions to fix these problems, with primary focus on revising the definition of "foreigners" and providing a clear criteria to facilitate the identification of a "nominee arrangement" under the FBA respectively. With the implementation of the proposed solutions, nominee arrangements will be eradicated over time, which would result in a more balanced playing field, which will both protect Thai businesses and promote foreign businesses in Thailand.

Keywords: Foreign Businesses, Nominee Arrangement, Foreign Business Laws, Legal Measures, Foreign Direct Investment

1. Introduction

Foreign direct investment plays a huge role in Thailand's development, because multinational companies bring technological advancement into the country, and fund capital investment which help to power Thailand's economic and fiscal development within the global economy. Many countries have tried to promote foreign direct investment by granting both tax and non-tax incentives to foreigners who are looking to establish a permanent legal establishment under its jurisdiction, to enable them to conduct promoted business activities in the country, which the local government believes is essential for the country's economic development. However, other parties harbor a contrary view, and they have sought to restrict foreign direct investment by limiting foreign ownership in certain business sectors, for fear that foreign control in certain business sectors could lead to unfair advantages over their own national businesses, which have fewer resources and are less technologically advanced than larger foreign corporations.[2]

The types of foreign ownership restrictions imposed in each country is mainly dependent on the degree of economic advancement, and on the internal fiscal and economic policy adopted by each country. For example, developed countries tend to have a relaxed approach and a more welcoming attitude towards foreign ownership (in the form of foreign direct investment) in its own country, while developing and less developed countries tend to adopt a more restrictive and protective approach towards foreign businesses, due to the fear that foreign domination and control in many business sectors could negatively impact the country's long term economic and fiscal development.

Foreign ownership in businesses in Thailand has always been restricted under the relevant laws and regulations, because Thailand is still a developing country, and thus, it is not ready to compete with heavily funded foreign corporations, which are looking to expand their businesses in

[2] ibid.

Thailand. Due to the foreign restrictions under the respective laws, foreigners have attempted to seek alternative solutions in order to conduct business in Thailand, and many risk-tolerant foreigners have tried to find illegal methods to circumvent the foreign ownership restrictions existing under Thai laws.[3]

2. Development of Foreign Business Laws in Thailand

Under Thai laws, foreigners and Thai nationals have equal rights on all legal matters, unless otherwise stated under the laws. Before 1972, foreigners had the same right to do business in Thailand as Thai nationals. However, in 1972, the Thai government passed the Announcement of the National Executive Council No. 281 (hereinafter referred to as the "**281 Announcement**"), which restricts certain rights of foreigners to invest in and conduct the reserved business activities which are stipulated under the 281 Announcement in Thailand. Under the 281 Announcement, a juristic person is considered an "alien", based on the number of foreigners and the capital contribution made by the foreigners in the juristic person, which engages in the reserved business activity in Thailand. In addition, foreigners were only allowed to do business in Thailand if they could find a Thai partner to co-invest and co-operate with the juristic person to engage in the reserved business activity with the foreigner(s). However, the Thai partners would hold the majority number of shares or contribute the majority of the capital contribution in the juristic entity, since foreign ownership was restricted to less than the majority amount of capital contributed by the foreigners. As a result, this meant that foreigners would have to give up ownership in the juristic entity in question to the Thai national(s), who would hold the

[3] Pugnatorius, 'Seven Deadly Sins: The Status Quo of Thailand's Foreign Business Act' (*Pugnatorius,* 16 October 2019) <https://pugnatorius.com/Foreign_Business_Act_B.E.2542/> accessed 25 October 2019.

majority number of shares in the juristic person.[4] Although, foreigners could apply for permission to conduct certain business activities which were reserved under the 281 Announcement, in order to operate the business activities as a 100% foreign-majority owned entity, such application process proved to be very difficult in practice, and often led to an unfavorable approval outcome. Therefore, many foreigners had to find other ways to carry out business in Thailand.[5]

In 1999, the 281 Announcement and its amendments were repealed and replaced by the Foreign Business Act B.E. 2542 (A.D. 1999), hereinafter referred to as the "**FBA"**, which adopted almost identical text and provisions from the 281 Announcement. However, under the FBA, the definition of "foreigners" no longer focused on the number of foreign shareholders in the juristic person, but rather, the definition of "foreigners" now placed emphasis on the number of shares held by the foreigners, and/or the amount of capital contribution made by the foreigners in the juristic entity in question.[6]

Similar to the 281 Announcement, the FBA restricted foreign ownership in the juristic person, which engaged in the reserved business activities specified in List Two and List Three annexed to the Act, to less than 50%, in order to encourage foreigners to conduct business activities in the form of a joint business operation with Thai nationals, based on the condition that Thai nationals hold a majority of the shares, and ultimately have more controlling interests in the juristic entity than the foreigners.

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[4] Lorenz & Partners, 'Rights and Protection of Minority Shareholders in Thailand' (*Lorenz-Partners,* May 2017) <https://www.lorenzpartners.com/download/thailand/NL1_8_8_E-Rights-and-Protection-of-Minority-Shareholders-in-Thailand-May1_7_.pdf> accessed 5 May 2019.

[5] Pugnatorius (n 3).

[6] Chatchawarl Sornsurarsdr and Chansilp Laosiriwut, 'Thai Nominee Shareholders: Aftermath Problem' (*CBSC,* 5 August 2010*)* <http://www.csbc-law.com/thai-law-insights/thai-nominee-shareholders-aftermath-problem.html> accessed 24 July 2019.

Furthermore, the FBA also contains provisions, which prohibit Thai nationals from assisting, aiding, abetting, and participating with the intention of holding it out as the Thai national's owned business, or holding shares in the juristic person on behalf of the foreigners with the objective of enabling the foreigners to circumvent the foreign ownership restrictions under the FBA. However, many foreigner still continue to seek out ways to avoid the foreign ownership restrictions under the FBA, since they do not wish to give control or other monetary benefits, such as dividend entitlements from the business operation, derived from the juristic entity to the Thai national(s), and the process of applying for a foreign business license under the FBA appears to be too complex, and often results in the Thai regulatory authorities handing down negative outcomes, which has discouraged many foreigners, who have instead sought to find alternative routes to do business in Thailand.[7]

The lack of a better alternative has driven many foreigners to set up a juristic person with a nominee arrangement, with the sole purpose of avoiding the foreign ownership restrictions imposed under the FBA.[8]

3. Problems of Nominee Arrangements in Thailand

When the 281 Announcement came into effect, it did not take into consideration the legal loopholes which would allow nominee arrangements to be created, since the definition of an "alien" merely focused on the number of foreign shareholders, and the amount of capital contribution made by the foreigners, without any consideration about the voting rights and other indirect control mechanisms, which may be exploited by foreigners seeking to avoid the foreign ownership restrictions established under the respective laws.

Since there are many ways in which a foreigner can legally own and control juristic persons, without having to hold the majority of the shares, or

[7] Pugnatorius (n 5).

[8] ibid.

providing the majority of the capital investment in the juristic entity, foreigners have used a backdoor channel to circumvent the foreign ownership restrictions under the 281 Announcement and ultimately, the FBA.[9] They have achieved this by setting up a juristic entity under Thai laws, and thereafter, permitted Thai nationals hold the majority of the shares which possess diluted voting rights (for example, ten (10) shares for one (1) vote), while the foreigners would hold a minority number of the shares which possess more voting rights per share than the preference shares held by the majority Thai shareholders.[10] Such arrangement is commonly known as a "**nominee arrangement**", which in effect implies a situation whereby a person (known as the "**nominee**") holds shares, and operates business activities in his or her capacity as the legal shareholder of the company on behalf of another person (known as the "**beneficial owner**") who is, in fact, the real owner and the beneficiary of the shares held by the nominee(s) for the purpose of protecting and hiding the real identity of the beneficial owner for the purpose of circumventing the foreign ownership restrictions under Thai law.[11]

A nominee arrangement is possible under Thai law, since under the Civil and Commercial Code of Thailand, companies can be set up with two (2) classes of shares, i.e. ordinary shares and preference shares. Preference shares can be given with different voting rights, and other types of benefits (such as the right to receive a higher dividend rate, or the right to appoint

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[9] ibid.

[10] ibid.

[11] Anupan Kijnichcheeva and Nampon Tonguthaisri, *Karn Hai Kwaam Chuaylheu Leu Sanubsanoon Leu Ruemgun Leu Teu Hoon Tan Kon Tang Daow Tarm Matra 36 Hang Por.Ror.Bor. Karn Prakorb Turakit Kong Kon Tang Daow Por.Sor. 2542* [*Assisting, Supporting and Holding Shares on Behalf of Foreigners under Section 36 of the Foreign Business Act B.E. 2542*] (Chulalongkorn Law Journal, 28(2) August 2011) (อนุพันธ์ กิจนิจชีวะ และ นำพล ทองอุทัยศรี, *การให้ความช่วยเหลือหรือสนับสนุน หรือร่วมกัน หรือถือหุ้นแทนคนต่างด้าวตามมาตรา 36 แห่ง พ.ร.บ การประกอบธุรกิจของคนต่างด้าว พ.ศ. 2542* (วารสารกฎหมาย คณะนิติศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย, ปีที่ 28 ฉบับที่ 2 สิงหาคม 2554)).

member(s) of the board of directors, etc.).[12] The lack of clear criteria on the characteristics and rights which are allowed to be given to the preference shares under Thai law, means that preference shares can have any rights as desired by the promoters and the shareholders of the company. Consequently, this has led to a situation where foreigners have used the loophole under Thai corporate laws to circumvent the foreign ownership restrictions under Thailand's foreign business laws, i.e. the 281 Announcement and the FBA.

From the perspective of corporate laws, the corporate structure of preference shares with diluted voting rights has been confirmed by the Office of the Council of States to be legally valid on the ground that the determination of rights and conditions associated with preference shares can be determined in accordance with the wills of the promoters of the juristic entity, without legal restrictions, since the determination of different voting rights or any other benefits of the preference shares does not cause any unfair disadvantages to the other shareholders of the company, and nor does the determination of different rights and benefits between the two (2) classes of shares (ordinary shares and preference shares) contradict or contravene the laws, public order, or good morals of the general public. Since the assignment of different rights and benefits to preference shares were deemed to be a private matter, therefore, this could be undertaken without any restrictions under the laws.[13]

In practice, a number of foreign investors have set up a juristic person, with Thai nationals holding the majority of the shares with fewer voting rights than the foreigners, who hold fewer number of shares, in order to ensure that the juristic person in question is regarded as a "Thai" company under the criteria stipulated under the FBA. Therefore, such juristic

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[12] Sopon Ratanakorn, *Kum Athibai Pramuan Kodmhai Pang Lae Panich Hoonsuan Borisut* [*Explanation of the Civil and Commercial Code: Companies*] (11th edn, Nitibannakarn Publishing House 2009) (โสภณ รัตนากร, *คำอธิบายประมวลกฎหมายแพ่งและพาณิชย์ หุ้นส่วนบริษัท* (พิมพ์ครั้งที่ 11, สำนักพิมพ์นิติบรรณการ พ.ศ. 2552)).

[13] ibid.

persons with nominee arrangements would fall outside the scope of a "foreigner" as defined under the FBA, and thus, such entity can freely engage in any business activity which is reserved under the laws, and which are intended to be operated exclusively by Thai nationals only. The use of nominee arrangements, coupled with a preference shareholding structure with diluted voting rights, thereby creates a perfect legal loophole for foreigners to skirt the boundaries of the laws of Thailand.

In addition, although both the 281 Announcement and the FBA contain provisions which prohibit nominee arrangements, however, the lack of a clear definition as to what constitutes a "nominee arrangement", or the factors which should be taken into consideration when contemplating what constitutes a "nominee arrangement" under the laws, has created problems with both the interpretation and the enforcement of the foreign business laws in Thailand, which has negatively impacted the credibility and reliability of the Thai legal system in the eyes of foreign investors who are seeking to invest in Thailand, as the foreigners view the legal system of Thailand as being unclear, unpredictable, and full of gray areas.

Furthermore, although the laws have established a regulatory authority to investigate and prosecute nominee arrangements in Thailand, however, in reality, only a few formal investigations have been conducted by the regulatory authority each year in a few selected industries, such as tourisms, bars and restaurants and property etc., most of which are small-sized business operations which do not cause any significant economic impact when compared to nominee arrangements existing in other sensitive business sectors, such as the telecommunication sectors, land transportation, air transportation, and agriculture, etc.

Therefore, the use of nominee arrangements is still widely practiced in Thailand, due to weak enforcement by the regulatory authority, and the complications in proving the true intentions between the Thai nominees and the foreign shareholders in respect to setting up such nominee arrangement. The lack of clear objective criteria for determining a nominee arrangement has compounded the problem as this renders it extremely

difficult for the regulatory authority to prosecute any wrongdoer for violations under the relevant laws.[14]

This is why a deeper analysis of the legal loopholes under the current foreign business laws of Thailand is important, in order to facilitate greater understanding of how these particular laws are failing at both ends of the spectrum i.e. both in terms of offering protection to real Thai businesses, and promoting foreigners to conduct business in Thailand.

4. Conclusion

The main objective of the FBA is to regulate how foreigners conduct business activities in Thailand, and to encourage foreigners to do business with Thai partners by setting up a Thai company together, which will result in the transfer of technology and knowledge, and a sharing of resources, with Thai persons. However, in reality, there are many foreigners, both natural persons and juristic entities, who/which have exploited the loopholes under Thai corporate laws, by setting up a business entity in Thailand and engaging a Thai national to hold shares on its behalf, in the form of a nominee arrangement, for the sole purpose of circumventing the foreign ownership restrictions under Thai laws.[15]

This is because the FBA focuses only on the foreign shareholding percentage and the amount of capital contributions made by the foreigners, without considering the voting powers and/or other indirect control mechanisms, which the foreigners may use to directly, or indirectly control the juristic person in question.

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[14] Athuek Asawanont, *Kodmhai Karn Prakorb Turakij Kong Kon Tang Daow Gub Nuk Kodmhai* [*Conducting Businesses by Foreigners and Foreign Lawyers*] (New Law Articles, 2007) (อธึก อัศวานันท์, กฎหมายการประกอบธุรกิจของคนต่างด้าว กับนักกฎหมายต่างด้าว (วารสารข่าวกฎหมายใหม่, 2550)).

[15] Chatchawarl Sornsurarsdr and Chansilp Laosiriwut, 'Thai Nominee Shareholders: Aftermath Problem' (*CBSC,* 5 August 2010*)* <http://www.csbc-law.com/thai-law-insights/thai-nominee-shareholders-aftermath-problem.html> accessed 24 July 2019.

In addition, although Section 36 of the FBA prohibits nominee arrangements, by stating that a Thai national who assists, aids, and abets, or participates, in the operation of a foreigner's business, which is specified in the Lists under the Act, or who operates a business in a manner which holds it out as the Thai national's sole business, or who hold shares on behalf of the foreigners, will be found to be in breach of the Act. However, in reality, very few parties have been prosecuted for these violations due to the difficulties relating to proving the factors that would exactly constitute a nominee arrangement and the limitations on the interpretation of the laws by the regulatory authority.

Despite the fact that there are many alternative ways for foreigners to correctly and legally conduct reserved business activities in Thailand, a significant number of foreign investors still elect to use a nominee arrangement due to its simplicity, cost effectiveness, and the low risk of enforcement by the Thai government authorities for violations of the FBA.

The author believes that foreign business laws in Thailand are in need of a major reform. Before doing so, the Thai government must firmly decide what is more important: (i) the promotion of foreign direct investment; or (ii) the protection of Thai business interests.

It has clearly been evidenced from past experience that sitting on both sides of the fence, and trying to have it both ways, is a policy that is clearly not in the best interests of Thailand, since Thai laws are neither protecting the interests of Thai businesses, and nor are they attracting foreign investors to do business in Thailand.[16] Therefore, in order to improve the efficiency of foreign business laws in Thailand, and their enforcement in respect to real world practices, the author would like to propose the following recommendations to resolve the problems relating to the use of nominee arrangements in Thailand, as follows:

[16] Anupan Kijnichcheeva and Nampon Tonguthaisri (n 11).

4.1 Revisions to the Definition of "Foreigners"

This solution involves a revision to the definition provided for a "foreigner", as stipulated under the FBA, so that it also includes both the direct and indirect controlling interests (in the form of voting rights and other indirect controlling mechanisms) of foreigners in the juristic person in question. The proposed revision to the definition of a "foreigner" under the FBA would greatly help to close the legal loopholes, which are currently prevalent under the existing foreign business laws of Thailand.

4.2 Revisions to the Criteria for a "Nominee Arrangement"

The proposed revision includes the relevant factors, which are taken into consideration by the regulatory authority, for determining a nominee arrangement, which shall include the following factors:

(a) Wealth and income of the Thai shareholder(s);

(b) Source of financing for the purchase of the shares, or for the initial capital contribution by the Thai shareholder;

(c) The voting rights and the dividend rights of the Thai shareholder(s) in the juristic person in questions, and its correlation to his/her proportion of the shareholding, or the capital contribution made in the juristic person in question;

(d) The history of attendance at the shareholders' meetings of the juristic person by the Thai shareholder(s);

(e) The power to nominate and/or remove members of the Board of Directors by the Thai shareholder(s);

(f) The level of participation in the management of the juristic person in question by the Thai shareholder(s); and

(g) The binding signatory powers, and the bank signatory powers of the director(s) of the juristic person in question.

The provision which prohibits nominee arrangements shall also clearly state the types of activities, or arrangements, which should be prohibited under the laws based on the grounds of a nominee arrangement, For example, execution of agreements or relevant documents between a

Thai national(s) and foreigners which involve giving, temporarily or permanently, legal ownerships and controlling interests in the shares, which are held by the Thai national, to the foreigners.

4.3 Update the Lists of Reserved Business Activities under the Act

The lists of reserved business activities, which are stipulated under the lists annexed to the FBA, must be updated with restrictions on foreign ownership in areas where there is an absolute necessity for such restrictions, i.e. restrictions on the grounds of national safety and national interests.

Alternatively, control mechanisms must be imposed on foreigners who are seeking to conduct business in Thailand, which will benefit the country, such as impositions on the amount of minimum capital requirement for foreign-majority owned entities, and requirements for the employment of Thai employees, and compulsory transfer of technology requirements, etc.

4.4 Simplification of the Foreign Business License Process

The application process for a foreign business license should be streamlined, so that it is clearer and faster, with consistent criteria on the information and the lists of documents required to be provided by the applicant, and the criteria adopted by the decision-making authority in granting approval. A simpler and more straightforward application procedure would encourage foreigners, who wish to operate reserved business activities in Thailand, to apply for a foreign business license, rather than pursuing the much cheaper, but illegal, nominee arrangement solution. Additionally, the application process should be available in English, since the majority of the applicants will be foreigners.

In this way, the foreigners can apply for the process by themselves, and it does not need to be processed via a third-party service provider, such as a law firm or an accounting firm.

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AN ANALYSIS OF PATENT TERM ADJUSTMENT FOR ADOPTION IN THAILAND*

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Abstract

This article focuses on the measure to compensate for the time taken to issue a patent by the Department of Intellectual Property by providing an extension of the term of a patent. In issuing each patent following an application filed to the patent office, the time period to examine and grant a patent could vary depending on a number of factors including complexity and fields of the invention. Moreover, in most cases, the long process results in a loss of revenue.

The patent term adjustment system does exist and is enforced in several countries. Thailand does not provide a similar measure to adjust the term of a patent issued later than a specified period.[1] According to the existing law, there are no specific provisions as to the time within which the whole process of registration and each step of the process must be completed. Although Thailand's administrative law affirms the right of individuals to bring a case before the Administrative Court where an administrative agency or a state official neglecting official duty required by

* This article is summarised and rearranged from the thesis "An Analysis of Patent Term Adjustment for Adoption in Thailand" Faculty of Law, Thammasat University, 2019.

[1] There is an extension limited to period for court proceedings under Section 16, 74 or 77 sexies, as provided in Section 35 of the Thai Patent Act which is not the same as the point of this article.

the law to be performed or performing such duties with unreasonable delay, there exist no determinative indication as to present that what exactly amounts to unreasonable delay. Hence, there is no guarantee that there will be no unreasonable delay in the patent registration process. Other laws cannot apply to this kind of cases because of the nature of patent. Therefore, individuals should also be able to receive a proper remedy for the delay in the patent registration process when such delay is not attributable to them.

This article presents the concepts and regulation of the United States, Singapore, and South Korea concerning the patent term adjustment system, and legal analysis in response to the ongoing problems in Thailand. The author suggests that Thailand's patent law should provide a remedy for patentees affected by procedural delay caused by the Patent Office. To this end, patentees should be compensated for the delay in the patent registration process by receiving an extension of the term of a patent.

Keywords: Patent, Term, Adjustment, Protection, Period, Issue, Process, Intellectual Property, Unreasonable Delay

1. Introduction

The news reported back in 2017 shows that more than 36,000 patent applications in Thailand were still pending, and more than 12,000 applications have been pending for more than 5 years due to lack of competent officials in the patent registration process, said the Minister of the Ministry of Commerce.[2] The inability to complete the process in a reasonable time period needs a solution, and it is necessary to look into Thai laws at the moment.

An exact period of time within which officials must complete the process of patent registration is not provided in the Patent Act, nor Ministerial Regulations and Notifications of the DIP. The right of an individual to file a case concerning unreasonable delay due to the conduct of administrative agencies could be inconvenient since it shall proceed in the Administrative Court, and administrative law does not fit for all disputes. Rights of persons are protected, and Thai people are treated equally before the Constitution of Thailand, and people are allowed to follow up and urge the State to perform the acts which directly benefit the people, according to Chapter 5, Duties of the State. However, no provision under this Chapter can be interpreted to deal with wait times in the patent registration. The Royal Decree on Good Public Governance still needs some time for the DIP to work with. Moreover, Section 29 of the Patent Act is one factor that leads to delay.

[2] Apiradee Tantraporn, 'Ekkachon Whan Dab Song Khom Chai Matra Sisibsi Taluang Panha Jod Sittibat Lasha [Individuals' Concerns Over Application of Section 44 For Delayed of Patent Grant]' (*Prachachat Turakij*, 5 March 2017) (อภิรดี ตันตราภรณ์, 'เอกชนหวั่นดาบสองคม ใช้ม.44 ทะลวงปัญหาจดสิทธิบัตรล่าช้า' (*ประชาชาติธุรกิจ*, 5 มีนาคม 2560) <https://www.prachachat.net/news_detail.php?newsid=1488708365> accessed 7 March 2018.

A patent is effective and enforceable only upon issuance, it is unenforceable after it expires.[3] According to the Thai Patent Act, the term of a patent starts from the application filing date which no one knows when exactly the patent will be granted and if a delay occurred at all. Although the protection is granted retroactively from the filing date, it will not change the fact that the time left for exploiting in the invention with the protection of an enforceable patent is less than the period granted by law. It is true that during patent-pending, there are many ways to make use of the invention even it has not been presented yet, but that reason is not enough to not look into other measures when possible.

As the problems presented, providing deadlines for the DIP in issuing a patent and addition of patent life for patented invention in case of delays due to the DIP's conducts will establish proper protection for patentees and set a standard in conducting the procedure.

2. Patent term adjustment

Patent term adjustment (PTA) is the term and concept existed in U.S. laws originally. The PTA system works when the patenting process delays due to causes stated by law, usually the conducts of the United States Patent and Trademark Office (USPTO). When the term of a patent is adjusted under the PTA system, an additional term will be added which means the extension of the life of a patent. However, delays due to the applicant shall be excluded. This article presents the PTA system in the United States and the other two countries that adopted the system; Singapore and South Korea.

[3] Robert Ashbrook, 'Patent Term and Patent Term Adjustment' (*Oppedahl Patent Law Firm LLC*, 9 May 2014) <http://www.oppedahl.com/images/dechert.pdf> accessed 21 August 2018.

2.1 United States

According to the U.S. Code, there are three types of guarantees which are, firstly, guarantee of prompt patent and trademark office responses (A delay)[4], secondly, guarantee of no more than 3-year application pendency (B delay),[5] and lastly, guarantee of adjustments for delays due to derivation proceedings, secrecy orders, and appeals (C delay).[6] These guarantees mean the law guarantees that the patenting process shall be conducted in the time limits as imposed by the law, and the patentee shall receive some remedy if the Office has failed to fulfill the tasks as guaranteed. The formula for calculating additional patent term is:

PTA = [A delay + B delay + C delay] - [Overlapping Delay] - [Applicant Delay]

The data of traditional total pendency presented by the Data Visualization Center of the USPTO shows that pendency tends to decrease over time. In the fiscal year 2016, total pendency varies between 24.2-26.6 months, in the fiscal year 2017 it is between 24.2-25 months, and the pendency decreases to between 23.8-24.4 months. As of February 2019, pendency is at 23.8 months.[7] According to the data, the U.S. patenting process is finished under 3 years.

2.2 Singapore

As a result of the FTA between the United States and Singapore signed on 6 May 2003,[8] PTA can be requested for applications filed on or

[4] 35 U.S.C., s 154(b)(1)(A).

[5] ibid, s 154(b)(1)(B).

[6] ibid, s 154(b)(1)(C).

[7] United States Patent and Trademark Office, 'Pendency' (*The United States Patent and Trademark Office*) <https://www.uspto.gov/corda/dashboards/patents/main.dashxml?CTNAVID=1004> accessed 17 April 2019.

[8] SIEC, 'Trade Policy Developments: USA-Singapore' (*Foreign Trade Information System*) <http://www.sice.oas.org/TPD/USA_SGP/USA_SGP_e.ASP> accessed 17 April 2019.

after 1 July 2004.[9] The time frame for processing a patent application in Singapore typically varies from 2-4 years.[10] The Registrar or the Intellectual Property Office of Singapore (IPOS) shall grant PTA if there are any of these following circumstances:[11]

Firstly, an unreasonable delay has occurred due to the Registrar in granting a patent,[12] which is when it takes more than 4 years from the filing date or more than 2 years from filing specific requests to issue a patent, but the delay caused by an applicant shall be excluded.[13]

Another scenario is when there has been a delay in granting the corresponding patent or related national phase patent, and the patent has received an extension of its term on the basis of such delay. So, the patent in Singapore may also get an extension if the Registrar allows, but it cannot exceed 5 years. [14]

2.3 South Korea

The PTA system was introduced in South Korea in 2012 as a result of the Korea-US FTA and can be requested for the applications filed on or after 15 March 2012.[15]

There are two circumstances that can include in PTA which are, firstly, when patent registration takes more than 4 years from the date a patent application has been made or, secondly when 3 years have passed

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[9] IPOS, 'Patents Infopack' (*Intellectual Property Office of Singapore*, 25 April 2017) <https://www.ipos.gov.sg/docs/default-source/resources-library/patents/infopacks/patents-infopack-(final)_25042017.pdf> accessed 17 April 2019.

[10] ibid.

[11] Patents Act of Singapore, s 36A(1).

[12] ibid, s 36A(1)(a).

[13] Patents Rules of Singapore, s 51A(5)(a)-(b).

[14] Patents Act of Singapore, s 36A(1), (4).

[15] Khushi Ram, Rajani Rajan, Krishna Rao Chintada, Ashok Arige and Ramesh Chakka, 'An Insight on The Patent Term Adjustment Provisions in Various Countries' (*IAEME Publication*) <https://www.iaeme.com/MasterAdmin/uploadfolder/IJIPR_09_01_001/IJIPR_09_01_001.pdf> accessed 4 July 2018.

from the date a request of examination of an application has been made. Between these two periods, the law takes into account only the latter period.[16] The periods of delay due to an applicant shall also be excluded from PTA.

3. Patent law in Thailand and legal issues

One of the many factors causing delays in Thailand's patenting process is the Patent Act itself.[17] Section 29 of the Patent Act allows up to 5 years after the publication of application to files for substantive examination.

The study[18] shows that, according to Section 29, after publication has been made, an applicant has to file a request for examination so to be confirmed that the invention is as described in Section 5, the examination request shall be submitted within 5 years from publication date. This means the maximum period of 5 years for filing examination request opens for research obstruction because, as shown in the research, 13.6% of applications were filed for examination on the last day of their rightful period. Moreover, most applications had no documents concerning examination results from foreign countries, even though more than 3 years already passed. The research analyses that the application filed for examination near the end of the 5-year period were not intended for patent, or the applicants might predict that their inventions were not

[16] Patent Act of Korea, art 92-2.

[17] Usawadee Sutapak, Kannikar Kijtiwatchakul, 'Tum Mai Karn Anumut Sittibat Nai Prated Thai Chai Wayla Narn: Preuttikum Brisut Ya Karm Chard Lae Chong Wang Thang Kot Mai [Why Patent Grant in Thailand Takes So Long: Conducts of Multinational Pharmaceutical Companies and Legal Loopholes]' (*Medicine-related Blog - Medical Monitoring and Development Center*, 28 December 2015) (อุษาวดี สุตะภักดิ์, กรรณิการ์ กิจติเวชกุล, 'ทำไมการอนุมัติสิทธิบัตรในประเทศไทยใช้เวลานาน: พฤติกรรมบริษัทยาข้ามชาติและช่องว่างทางกฎหมาย' (*Blog สถานการณ์ระบบยา –ศูนย์วิชาการเฝ้าระวังและพัฒนาระบบยา,* 28 ธันวาคม 2558)) <http://www.thaidrugwatch.org/blog/?p=1059> accessed 25 July 2019.

[18] ibid.

patentable but filed for examination just to keep other people away. Finally, the research's conclusion is that Section 29 shall be revised by reducing the 5-year period to 6 months or 1 year.[19] Even though Section 29 is the right of an applicant to file for examination any time before 5 years end, the author would like to present it as an interesting issue to discuss along with an extension of the patent term that this article focuses on which shall be granted only for delays from the DIP excluding delays from applicants. In the case that an applicant has done or neglected anything to slow down the patenting process, it will amount to applicant delay that a period of adjustment will not be granted for it.

Not only the problem in Section 29, but there is also no existence of any specific provision dealing with time limits of some essential steps in the registration process or the whole process. Therefore, it is necessary to look into issues in other laws.

Under administrative law, staff of the DIP who conduct the patent registration process are "officials" who perform administrative acts, so if they neglect the duty required by law to be performed or perform the required duty with unreasonable delay, the Administrative Court has jurisdiction over such case. However, solving a patent case with administrative law is not always suitable due to the nature of patent. Administrative Court orders 45/2547 and 630/2547 show that the Applicant, who is the same person for these cases, believed that the DIP's conduct in the patenting process was unreasonable delay. The Applicant contended that the officials of the DIP exercised administrative power in the way that slowed down the examination process, and thus, caused damage to the Applicant. In the end, the Applicant did not get damages and did not get any other remedy. If there were a law to grant an extension of the term of a patent, the Applicant could be able to have the patent term extended if the requirements for PTA were fulfilled.

[19] ibid.

Next, Section 51 in Chapter 5 of the Constitution of Thailand B.E. 2560(2017) provides the right for people to follow up and urge the State to perform the acts which are directly beneficial to the people; therefore only the circumstances provided under Chapter 5 or "Duties of the State" shall raise such right for people. However, there is no provision to be interpreted in the way that this article is finding.

Lastly, Section 6 of the Royal Decree on Good Public Governance B.E. 2546(2003) as amended up to No.2 B.E.2562(2019) presents that the Government has to be responsible for taking care of the State and the people as provided in the Decree. It is undeniable that public tasks, for example, conducting the patent registration process, are for the Government to fulfill, not different from public health care or education. Since the context of Section 6 and some other provisions in the Decree have existed from 2003, it is fair to say that there are problems in law enforcement which is the issue in practice.

As the problems in the lack of laws and enforcement present, the author would like to analyse the PTA system in the U.S., Singapore, and South Korea to find conclusion and recommendation for Thai law.

4. Conclusion and recommendations

As a developing country, Thailand has been targeted by multinationals to seek revenues. Most of the patent applications filed and registered patents in Thailand are from foreign countries, while Thai inventors share only a small proportion. When the patent term is to be adjusted and extended, it will benefit patentees which mostly are foreigners, and that could bring negative effects. However, there are not only foreigners who hold patents in Thailand. Thai people, even with less competitive ability, shall not be neglected and treated poorly because they, as inventors, shall also be rewarded from all the effort they put in creating the inventions.

After a careful study and consideration, the author would like to propose that the Patent Act shall be revised in these following matters:

Firstly, there shall be only one ground for adjustment, that is, an application for which a patent is granted after 5 years pending shall be able to get an extension of the patent term. A patent life shall be extended day-for-day or one day of delay means one day of extension. However, the maximum additional period that can be granted is 5 years. The reason is that where the maximum total pendency in U.S law is at 3 years, 2 or 4 years for Singapore, and 3 or 4 years for South Korea, these countries have a more advanced and effective patent system to manage the issue of a patent in those periods. The period of 3 or 4 years seems ideal for the patent grant but Thailand might not be ready to do it in that period, so the period of 5 years should be appropriate. The news in the Introduction section also shows the number of patent applications pending for more than 5 years, it could be interpreted that the wait time later than 5 years is ineffective. The patent registration process should not take longer than 5 years because it will show the ineffectiveness of the patent system which the PTA system is to improve it and make a solution.

Secondly, grounds for the PTA should be restricted to the delay attributable to officials involved in the patent registration process. Any delay caused by patent applicants should provide no ground for the PTA.

Lastly, an extension shall not be automatically provided by the DIP as this shall be the conduct of patentee. After the patent has been issued, the patentee shall file for an extension of the patent term within 3 months if it is possible to get a PTA for that patent.

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THE ROLE OF GOOD FAITH IN PRE-CONTRACTUAL LIABILITY*

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Abstract

The breaking off of the negotiation phase, which is contrary to the good faith principle and cause the damages to the party, is unfair to the aggrieved party if the law cannot be enforced against the party who acts in bad faith during the pre-contractual stage, particularly when the parties expect to reach the final agreement and preliminarily commence the work without having the formal execution of written agreement due to the mutual trust, strict due date, or any demonstrate commitment. Such breaking off contrary to the good faith principle causes the damage to the aggrieved party especially with the project which has significant and large-scale investment value who may not be able to claim the pre-contractual liability from the other party.

Under the Thai Civil and Commercial Code ("CCC") the issue remainings unclear and there is no practical guideline of Thai court that interprets the pre-contractual liability principle. Unlike Thai law, some European countries such as Germany and France have annexed the pre-contractual liability concept phase as their domestic contract law covering pre-contractual liability cases against the party who breaks off the negotiation with bad faith.

* This article is summarised and rearranged from the Independent Study "The Role of Good Faith in Pre-Contractual Liability", Faculty of Law, Thammasat University, 2019.

According to the above problem of Thai law, this article will address the comparative study of pre-contractual liability concept with the analysis of the role of good faith principle in pre-contractual liability under the English law, which has never acknowledged the good faith principle under contract law.

The analysis demonstrates how the court could apply the good faith principle under CCC Section 3, 4 and 5 to the pre-contractual liability case as well as an alternative solution of amending the CCC to solve the said problems of pre-contractual liability case in Thailand.

Keywords: Pre-Contractual Liability, Duty to Negotiate in Good Faith, Role of Good Faith

1. Introduction

In the business context, whenever two or more parties, whether individual persons or juristic persons, decide to start the negotiation or bargain procedure, the parties have high expectations to reach the last stage of signing the final agreement or contract in order to commence the business engagement for their beneficial and mutual profits. Also, the negotiation process is considered as an important mechanism for business parties i.e. buyer/ seller, service provider/ service receiver to achieve their ultimate goal in exchanges within business markets especially in terms of business.

The parties normally make the pre-contractual agreement either in verbal form or written form e.g. e-mail correspondence or engagement as their evidence of agreeable terms and condition which contained with the scope of work, quotation fee, and action plan in order to avoid misunderstanding the details when commencing the scope of works and signing the final agreement especially when the parties who have the long business relationship together. For example, the construction company who has been working with the customer i.e. real estate developer for 20 years in many projects may verbally agree with its customer to build the housing project in Thailand during the pre-contractual phase without the final agreement since both parties have a strong business relationship due to some reasons such as the limitation time of schedule of work, or the internal process which takes time for approval by customer's committee. Later on, if the customers break off the contract with the construction company on the project which has started working in advance without the agreement. The construction company might not be able to claim the pre-contractual liability from the customer during the pre-contractual phase under the CCC. In addition, if the fact provides that the customer has no intention to reach the final agreement at the beginning and has bad faith to enter into a bargain procedure because just only to have access to some "Business Secrets". Such pre-contractual liability should be able to claim

with the party who contrary to the good faith principle under Thai contract law.

An example case from overseas regarding the pre-contractual liability during pre-contractual phase is SIGA v. PharmAthene[1]. The fact was summarized as follows:

SIGA Technologies, Inc. ("SIGA") entered into a bridge loan and merger agreement with Pharmathene, Inc. ("Pharmathene"), Inc. to solve its financial hardship which had been dropped out. Under the term and condition of such agreement, the parties agreed that the parties would negotiate in good faith in the License agreement (LATS) attached thereof. Later on, the financial status of SIGA became profitable and turned the good sign of business operation, SIGA decided to exercise its right to terminate the merger agreement with Pharmathene and refused to negotiate under the LATS accordingly. Such termination by SIGA's bad faith caused the damage to Pharmathene from breaking off the duty to negotiate in good faith under such agreement and the LATS. For the judgement, the judge applied the Delaware law as agreed by both parties to solve this case and encompassed the activity that good faith principle was at the heart of the case, SIGA had breached its contractual obligation to negotiate in good faith, as an express contractual obligation to negotiate in good faith was binding on the contracting parties.

Overview of pre-contractual liability concept in Civil Law systems, the duty of negotiation in good faith have been stipulated the principle in its domestic code and used in practice for many countries such as Germany[2], Dutch[3], Italy[4] as their general principle to cover the case of breaking off the negotiation wrongfully by the act of bad faith, while Thai Law does not enact such principle in its domestic contract law.

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[1] *SIGA Techs. Inc. v. PharmAthene, Inc,* 67 A.3d 330, 347 (Del. 2013).

[2] German Civil Code, s 242.

[3] Dutch Civil Code, art 248.

[4] Italian Civil Code, art 1337.

On the other hand, in the Common law, English law does not recognize the general concept of good faith based on the traditional and historical and strongly denied to apply in business commercial[5] cases. However, in the recent case of English law, the role of implied good faith principle has been recognized and implied throughout the Court Decision[6] to justify the aggrieved party. It seems that the English court starts to recognize the good faith principle depending on the duty and the context of a contract or agreement which shall be expanded to imply by the court to the pre-contractual liability case, especially in the "relational" contract which requires and involves with the long-term relationship of the parties.

Therefore, this next chapter shall demonstrate the problem of pre-contractual liability in Thailand under the CCC and in practice since the party cannot claim the pre-contractual liability which has not yet occurred during the negotiation stage since the contractual obligation "rights" to exercise with each other.

2. Problem of pre-contractual liability in Thailand

Juristic acts under the CCC is stipulated in Section 149 stating that "juristic acts are voluntary lawful acts, the immediate purpose of which is to establish between persons juristic relations, to create, modify, transfer, preserve or extinguish rights."

The juristic acts in Thailand may be divided into 2 types which are the bilateral juristic act and unilateral juristic acts such as promise, offer, invitation to treat,, etc. The legal status of formation of contract under Thai law to be created the obligation or "Contractual obligation" binding between the parties, the declaration of intention of both parties (offer and acceptance) must be met, whilst the legal status of pre-contractual liability during the negotiation stage, the contractual obligation or the declaration of

[5] *Walford v Miles.* [1992] 2 AC 128.

[6] *Yam Seng Pte Ltd v International Trade Corporation Ltd* [2013] EWHC 111.

intention of both parties has not yet occurred which the party has no right to claim the liability which contrary to good faith[7] principle.

On the other hand, the principle of good faith under the CCC is stipulated under Section 5 which was based on and influenced by Roman law. Although, the good faith principle is regarded as the general principle which is universally applicable (Generalkauseln), the interpretation and implementation of this principle are still confusing and there is no clear guidance for a judge when applying the principle. Some legal professionals and practitioners in Thailand have different viewpoints on this principle in contract law.

As such, the good faith principle under the CCC can be rarely seen according to Thailand's Court Decision using such principle by the judge to justify the parties in the situation where the contract terms of business commercial take advantage of the other especially in the case of negotiation in bad faith and sudden walk away with the damages and expenses.

Regarding the good faith principle, it can be seen that the Thai court admitted the general principle of good faith in many kinds of good faith throughout the court judgements in the past. For example the court applied the good faith principle to estoppel by conduct[8] or to identify the bad conduct[9] or even to prevent the bad faith[10]. However, it has never seen the principle of good faith applied in the case of breaking off the negotiation contrary to good faith in the pre-contractual stage.

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7 Jampee Sotthibandhu, Rak Kham Rab Pid Korn Sanya [Pre-contractual liability] (3th edn, Winyuchon 2005) 45 (จำปี โสตถิพันธุ์, หลักความรับผิดก่อนสัญญา, (พิมพ์ครั้งที่ 3: วิญญูชน 2548)) 45.

8 Supreme Court case no. 1082/2533.

9 Supreme Court case no. 1538/2508.

10 Supreme Court case no. 371/2534.

3. The role of good faith principle in pre-contractual liability in foreign laws

3.1 The role of good faith principle in Civil Law

Most EU member countries have apparently recognized the notion of good faith principle as the general law and incorporated in their Civil codes as domestic law especially in the case of the pre-contractual stage which requires the party to negotiate in good faith and fair dealing. The following are the sample of Civil Code provisions of the Civil Law systems in the EU.

In the German civil law, section 242 provides that "everyone must perform his contract in the manner required by good faith and fair dealing (TreuundGlauben) taking into consideration the general practice in commerce".

In the Dutch civil law, article 6:2 provides that "Good faith will not only supplement obligations arising from contract but may also modify and extinguish them".

Under section 1337 of Italian civil law, it is required the contracting parties to act with good faith in any stages of the relationships i.e. negotiation stage, contracting stage, while France civil law, Napoleonic Code under article 2268 is stipulated that "Good faith is always presumed, and it is on the person who alleges bad faith to prove it." as the general term and provision.

Therefore, in most Civil Law system countries, the concept of good faith is regarded as the general law and the highest norm to be respected in contractual and pre-contractual obligation.

4. The role of good faith principle in pre-contractual liability in English Law

Under English law, the Common Law system, the good faith principle has been strongly denied in the contract law unlike the Civil law system. English law is more focusing on the individualism which means that they

respect the freedom of contract of the parties to freely negotiate and pursue their own interest. Also, English law is based on the "judicial precedent" or "judge make law"[11]. It means that English law is not based on the written code, but it solely depends on the case precedent. Therefore, the termination of negotiation does not breach English contract law since, in England contract law, the formation of a contract requires (1) offer and acceptance (2) consideration (3) an intention to be legally bound.

Although, the offer can be terminated as long as it does not have the consideration element in such offer or the offer has made of deed required by the law[12]. English law does not provide the principle of pre-contractual liability during the negotiation process, but the English court prefers to develop the piecemeal solution instead of applying the good faith principle to override the fact of the case[13]. Therefore, based on the case precedents in the past, the good faith principle in contract law has been not recognized and used much in the Court Decision as an exceptional case.

However, in the recent case[14] of the English court, the role of good faith has implied in the contract law where it is lack of good commercial business in respect of "relational contract" as the long-term contractual relationships and specific the special characteristics to scope such imply of the good faith principle in that case to justify the party.

This can be seen that the perception of good faith principle in English law has been changed and shown up to the spotlight to be considered and focused on by many legislators and law practitioners in

[11] Lloyd Duhaime, 'The Common Law Legal Definition' (*Duhaime's Law Dictionary*) <http://www.duhaime.org/LegalDictionary/C/CommonLaw.aspx> accessed 12 December 2019.

[12] *Routledge v Grant (1828)* 4 Bing 653; 130 ER 920.

[13] *Interfoto Picture Library Ltd v Stiletto Visual Programmes Ltd* [1989] QB 433.

[14] *Bates & Ors v Post Office Limited* [2019] EWHC 606.

England. This will be a big impact in English contract law in terms of good faith principle and provide the guidance for the next case of pre-contractual liability and the role of good faith principle with the relational contract.

Therefore, the recent cases can imply that the English court applies the good faith principle more widely to the commercial contract. However, this case is also reminded the English court that, which applies the good faith principle to the case, should not overarch the real intention of mutual agreement by the parties. Nevertheless, it shall be a good sign of English law that it has acknowledged the good faith principle, besides the utmost good faith case, to justify the suffering party from breaking off the "relational' contract.

In this regard, the Thai court may adapt the recent English court case to imply the good faith to justify the parties in case of pre-contractual liability in Thailand.

4. Recommendation

As mentioned earlier, the duty of good faith during the pre-contractual negotiation under Thai law has not yet been recognized since there has never been a case for the court to interpret the good faith principle to justify the party in this regard, even though the principle of good faith is considered as the general principle among the contract law.

Also, under the tort law of the CCC, the "rights" before the formation of a contract are not protected. As such, the pre-contractual liability in the negotiation phase cannot be claimed by the party and the pre-contractual obligation has not existed.

Therefore, in order to solve the issue of pre-contractual liability during the negotiation, the author would like to propose the following alternative solutions for applying it under Thai law.

4.1 To amend the CCC

In order to draw up the requirement of the parties and the validity of pre-contractual obligation during the negotiation phase, the CCC should add the pre-contractual principle to adjust and apply with the pre-contractual liability case like the other EU counties i.e. Germany, Italy, France.

Thus, please be advised to amend section 5 of the CCC according to the German Civil Law to extend the pre-contractual stage as follows:

Section 5 "*Every person must, in the exercise of his rights and in the performance of his obligations, act in good faith.*

"The rights in paragraph one shall be exercised and performed including but not limited to the period of the negotiation and formation of the legitimacy"

However, the process for amendment of the CCC might take long time to be considered and approved by the cabinet. Therefore, the following alternative option shall be considered to solve the current issue under Thai law.

4.2 To interpret the good faith principle under section 5 of the CCC with the analogy/ general principle under section 4 of the CCC

Of course, if the court or the legal practitioner can interpret and override the intention or fact of the contracting parties wherever they want, the interpretation of good faith principle in each case would be too subjective and vague according to the individual discretion. While section 5 of the CCC does not entail the duty of good faith during the pre-contractual stage, therefore section 4 of the CCC as the general principle is considered to analogy the principle of good faith and extend such rights covering to the pre-contractual stage.

Therefore, the author would like to purpose the criteria for the Thai court applying the good faith principle with analogy methods under Section

5 and Section 4 as the piecemeal solution by considering the level of the party's expectation of reaching the final contract/ agreement and the degree of significant investment or substantial financial impact of the project to justify the suffering party especially in the case of a big project with the high value of investment i.e. Joint venture company.

In summary, the author would like to highlight that the recommendation for the interpretation option to the Thai court by implying the general principle of good faith under section 5 and 4 to apply the case of pre-contractual liability considering with the clear criteria as provided above case-by-case basis and avoid the subjective discretion and bias of judge rather than considering to the amendment of CCC or stipulation of the specific law to be in accordance with other European countries.

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SOME LEGAL ISSUES OF BIOMETRIC DATA PROTECTION IN THAILAND *

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Abstract

Biometrics is a technology that can measure and analyze the physiological and behavioral characteristics of a person. Unlike a password, Biometrics data is hard to fake or steal. Since a person was born, he or she would have his or her specific fingerprints, iris, or facial which are unlike others. Biometrics is so convenient that it can identify persons from his or her own physiological or behavioral characteristics. However, Biometrics data is specific for each person. Hence, it could not be changed. Would it be dangerous if someone could hack, fake, or use our biometrics data, or is it dangerous if someone uses our Biometrics data in transactions? Is there any law in Thailand that could protect our Biometrics data in practice? Thailand has many laws that mention the rule for the protection of biometric data. Especially, The Personal Data Protection Act B.E.2562 ("PDPA") which is the first data protection act of Thailand. It provides a significant rule for the collection, use, and disclosure of personal data including biometric data. However, the PDPA is the first personal data protection act in Thailand which is very new. It provides only general and broad rules for processing all types of personal data including the biometric data which is mentioned in the Act as only a type of "personal data". There

* This article is summarised and rearranged from the thesis "Some Legal Issues of Biometric Data Protection in Thailand", Faculty of Law, Thammasat University, 2019.

are limitations to existing laws in Thailand to protect biometric data. It has many risks in the collection, use, and disclose of Biometric data. The provisions in The Personal Data Protection Act B.E.2562 remain unresolved in practice. Hence, This article will study the important practical issues that could happen with the PDPA which are the issues of “public interest”, “substantial public interest”, “explicit consent”, “civil liability” and “compensation”. The study of the General Data Protection Regulation of the EU (GDPR) (as a general rule followed by the PDPA), the UK Data Protection Act 2018, along with the UK’s Information Commissioner’s Office (to know how the member states provide the rules in accordance with the GDPR), and Illinois Biometric Information Privacy Act (as the first Biometric data protection act of USA) would be the best examples for Thailand to amend the act and to have a guideline for processing biometric data in order to enable it to govern the issues practically.

Keywords: Biometric Data, Personal Data, Data Protection

1. Introduction

Recognition Technologies play an important role in peoples' lives. Students or employees may be required to identify themselves at schools or workplaces by scanning students' or employees' cards. Currently, many schools and companies are using technologies that can recognize and identify persons. Instead of scanning students' or employees' cards, the technologies nowadays can identify persons by scanning their fingerprints, facials, or irises in order to identify them.[1] In today's world, many airports around the world use recognition technology to detect fingerprints or iris to identify passengers.[2] These technologies are also part of our daily lives such as a smartphone. Many smartphone brands provide the technology of fingerprints and facial recognition to unlock the phone. The technologies also have been used for banking businesses. That is, Mobile banking services have become one of the most important applications on the Internet being provided by most of the banks all over the world. The end-user can manage the accounts or make some payments without being forced to go to the physical bank office. All the technologies mention earlier are called "Biometrics". which is the word derived from Greek.[3] "Bio" means "life", "Metrics" means "to measure". There are two principal types[4] of biometrics which are; (1) physiological, such as, fingerprints, iris, and facial recognition, and (2) behavioral characteristics, such as, gait, voice, and signature

[1] Joss Fong, 'What facial recognition steals from us' (*VOX*, 10 December 2019) <https://www.vox.com/recode/2019/12/10/21003466/facial-recognition-anonymity-explained-video> accessed 10 January 2020.

[2] Webfact, 'VIDEO: Fingerprint and facial recognition now scanning passengers at Don Mueang Airport' (*ThaiVisa Forum*, 27 May 2019) <https://forum.thaivisa.com/topic/1103036-video-fingerprint-and-facial-recognition-now-scanning-passengers-at-don-mueang-airport/> accessed 6 November 2019.

[3] JAMMI ASHOK, VAKA SHIVASHANKAR, P.V.G.S.MUDIRAJ, 'AN OVERVIEW OF BIOMETRICS' (2010) 2(7) International Journal on Computer Science and Engineering' 2402-8.

[4] Shimon K Modi, *Biometrics in Identity Management: Concepts to Applications* (Artech House, Norwood 2011) 3.

recognition. Apart from biometrics that we have already known, for example, there are many other types of biometrics such as, retina scanning, DNA matching, vein recognition, etc.

2. Privacy concern of biometric data

Currently, we see the collection and use of Biometrics in many private and public organizations. For example, all the district offices in Bangkok have been using the technology of Biometrics on fingerprints collection in order to identify citizens.[5] Besides, due to the lack of technology, government sections may empower private sections to collect Biometrics data. For example, the Ministry of foreign affairs is going to collect the irises' data of citizens. Like other government sectors, the ministry does not collect Biometric data by itself due to the lack of technology. Hence, It empowers a private company to collect Biometrics data of citizens. What could be a guarantee that the government or private company would process our Biometric data properly? Does Thailand have a law that protects the collection, use, and disclosure of biometric data by the government or private section practically?

3. Five practical issues of the Personal Data Protection Act B.E. 2562 ("PDPA")

This article has found that Thailand does not have specific laws that protect the processing of Biometric Data in enough detail to be practically applicable. However, the protection of Biometric data is mentioned in many laws that are the Constitution of the Kingdom of Thailand B.E. 2560, Thailand Civil and Commercial Code, Thailand Penal Code, Computer-Related Crime Act (No.2) B.E 2560, Official Information ACT, Electronic Transaction Acts B.E. 2544. Also, the Personal Data Protection Act B.E.2562

[5] ThaiPR.net, 'Kor Tor Mor Num Rong Tum Bat Pracham Tua Doi Chai Rabob Computer Pim Lai Niw-mue [Bangkok Launched a Plan to use Fingerproint ID Card System]' (*RYT9*, 27 January 2004) (กทม.นำร่องทำบัตรประจำตัวประชาชนโดยใช้ระบบคอมพิวเตอร์พิมพ์ลายนิ้วมือ (*RYT9*, 27 January 2004)) <https://www.ryt9.com/s/prg/128254> accessed 4 April 2020.

which is the first personal data protection act of Thailand may have five practical problems that could occur in the processing and protection of Biometric data in practice.

(1) Issue of public interest: The PDPA provides the significant rule for the collection, use, and disclosure of personal data that must be consented by the data subject, except for the use for the "public interest". However, it could be said that all state missions are considered to be done for the public interest. There is no need for the state to seek our consent to collect, use, or disclose our Biometric data. As a result, the citizens could not sue the government or private sector for their acts. Since the PDPA does not provide the definition, guidelines, or scope for the processing of Biometric data relating to the public interest. The scope of public interest needs to be addressed in order to process Biometric data in practice.

(2) Issue of substantial public interest: Since the PDPA provides the condition to collect Biometric data beyond general personal data by prescribes the word "substantial public interest" for Biometric data apart from the "public interest" for general personal data. However, the PDPA does not define the word "substantial public interest" for the processing of Biometric data. Then the definition and scope of substantial public interest need to be considered in order to process Biometric data practically in order to know the difference between the "public interest" and "substantial public interest".

(3) Issue of explicit consent: In Thailand, the PDPA follows the rule of processing Biometric data of the GDPR by having the PDPA section 26 which states that "...collection of Personal Data pertaining to...Biometric data...is prohibited, without the explicit consent from the data subject..." However, the PDPA does not define the terms "explicit consent". Hence, there would be a problem in the processing of the Biometric data in practice in order to know the difference between "consent" and "explicit consent".

(4) Issue of civil liability: the problem is that the PDPA section 77 provides the words "causes damages to the data subject". The word "causes damages" shall have the same rule as the tort law that there

needs to have actual damages to the data subject. Practically, there would be an argument against an injured person under section 77. The controller who violates the PDPA may argue to dismiss the case that he only violates the PDPA by processing Biometric data without the data subject's consent for instance, but there are no damages to the data subject yet. This provision seems to contradict the purpose of the PDPA which has the purpose to protect the personal data by controlling the controller and the processor not to violate the PDPA.

(5) Issue of compensation: If there are many times of the violation of the PDPA but actual damages still not occur. For example, a grocery store uses facial recognition by storing faces of customers many times without their consent. The customers as the data subject may not have a chance to claim for compensation since they could not know the exact or amount of damages occurring to them. It is very hard for them to show evidence of their damages to the court. As a result, it would be a problem for them to claim compensation in practice which is contradicted to PDPA that has the purpose to fully protect the personal data.

4. The solutions for the five practical issues in foreign countries

The study of the General Data Protection Regulation (GDPR) of the EU (as a general rule followed by the PDPA), the UK Data Protection Act 2018 (DPA 2018) along with the UK's Information Commissioner's Office (ICO) (as the member state following the rule of the GDPR), and Illinois Biometric Information Privacy Act (BIPA) (as the first Biometric data protection act of USA) would be the best examples for Thailand to amend Thai law and to have a guideline for processing biometric data in order to enable it to govern the issues practically.

(1) Issue of public interest: Since the GDPR mentions the terms of processing the personal data in article 5(1) (a) which is the principle of lawfulness, fairness, and transparency. Also, the controller needs to meet one of the six conditions in the GDPR article 6(1) which is known as "lawful

ground". "Public interest" is one the lawful grounds prescribed in the GDPR article 6 (1)(e) "processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;..." The problem is, the GDPR does not define the term of "public interest".

As the study of the UK Data Protection 2018 ("DPA 2018"), normally, the terms prescribed in the DPA 2018 part 2 provide the same meaning as the GDPR. In some cases, the DPA 2018 modifies, clarifies, and supplements the GDPR since the GDPR does not provide some terms. For example, in the context of public interest, the DPA 2018 supplements the rules of processing public interest by prescribing the DPA 2018 section 7 which provides that

"... (1) For the purposes of the GDPR, the following (and only the following) are" "public authorities" and "public bodies" "under the law of the United Kingdom— (a) a public authority as defined by the Freedom of Information Act 2000",... "(2) An authority or body that falls within subsection (1) is only" a "public authority" or "public body" for the purposes of the GDPR when "performing a task carried out in the public interest or in the exercise of official authority vested in it..."

Moreover, in the context of public interest, the DPA 2018 section 8 also provides a non-exhaustive list of examples of "Lawfulness of processing public interest" which refer to the GDPR article 6(1)(e) which states that

"In Article 6(1) of the GDPR (lawfulness of processing), the reference in point (e) to processing of personal data that is necessary for the performance of a task carried out in the public interest ..."

As the DPA 2018 sections 7 and 8 provide only examples list of processing of public interest tasks. The Information Commissioner's Office (ICO) which is the guideline for using the GDPR and the DPA 2018 in the UK

then needs to comes to describes. The ICO provides the measurement[6] that even if the processing will fall outside the list provided in the DPA 2018 section 8, but it is still considered to be a public interest task by considering on the nature of the function not the nature of the organization., e.g.:

(a) "The administration of justice processes personal data for the public interest task should be able to rely on the GDPR article 6(1)(e)"

(b) "A private electric company does not fall within the definition of public authorities in the DPA 2018. However, the company is considered to be public authorities as it carries the function of providing public interest. It should be able to rely on the GDPR article 6(1)(e)"

Moreover, the organization must specify the relevant task and be able to demonstrate that there are no other reasonable and less intrusive means to achieve that purpose.

(2) Issue of substantial public interest: According to the processing of the special category data of the DPA 2018 and the ICO, the Biometric data as one of the special category data which needs more protection because it is sensitive data. To process Biometric data, the controller needs to concern 5 Steps:[7]

Step 1: Consider the lawful basis according to the GDPR Article 6 "processing of personal data shall be lawful"[8]

Step 2: Consider the separate 10 conditions provided for processing according to the GDPR article 9. "processing of special categories of personal data"[9]

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[6] Information Commissioner's Office, 'Public task' (*ICO.*) <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/public-task/> accessed 22 May 2020.

[7] Information Commissioner's Office, 'Special category data' (*ICO.*) <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/special-category-data/> accessed 5 May 2020.

[8] General Data Protection Regulation (GDPR) art 6.

[9] ibid, art 9.

Step 3: Consider the requirement for the controller to meet additional conditions set out in the DPA 2018 schedule 1 part 2. Since the GDPR article 9(g) states the rule to process special category data relating to the substantial public interest. However, it does not define the substantial public interest. Then the DPA 2018 Schedule 1 part 2[10] provides the 23 substantial public interest conditions.

The controller must identify which of these conditions appears to most closely reflect his purpose. The controller needs to demonstrate that specific processing is "necessary for reasons of substantial public interest", on a case-by-case basis. A generic public interest is not enough since the public interest covers a wide range of society. Also, the controller needs to make specific arguments about the concrete wider benefits of the processing.

Step 4: The controller must determine his or her conditions for processing Biometric data as special category data. There are also needs to have an 'appropriate policy document' in place in order to meet a UK Schedule 1 condition for processing in the DPA 2018.

Step 5: Lastly, for any type of processing that is likely to be high risk, the controller needs to complete a data protection impact assessment (DPIA).

(3) Issue of explicit consent: The ICO acknowledges that the GDPR does not provide a clear distinction between consent and explicit consent. However, the ICO provides that the "Explicit consent is not defined in the GDPR, but must meet the usual GDPR standard for consent." In particular, "it must be freely given, specific, affirmative (opt-in) and unambiguous, and able to be withdrawn at any time. In practice, the three extra requirements for consent to be 'explicit' are likely to be"[11]

[10] Data Protection Act 2018 (DPA) Schedule 1 part 2.

[11] Information Commissioner's Office, 'What are the condition for processing?' (*ICO.*) <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-

1. "explicit consent must be confirmed in a clear statement (whether oral or written), rather than by any other type of affirmative action;"

2. "it must specify the nature of the special category data; and"

3. "it should be separate from any other consents you are seeking"

(4) Issue of civil liability: The Civil Liability for violation of the Illinois Biometric Information Privacy Act ("BIPA") was introduced as "Right of action" The BIPA provides the rules of the right of action in the BIPA section 20 which prescribes that *"Right of action. Any person aggrieved by a violation of this Act shall have a right of action"*

From the BIPA, it set out that a person can be sued if he fails to inform opt-in consent for collecting biometric data. Moreover, data subjects mealy have to prove only that their biometric privacy is injured but they do not need to prove other injuries like identity fraud or physical harm. There also be the study case of The Illinois Supreme Court mentioned to this rule, that is, *Rosenbach v. Six Flags.*[12] The defendant violated the BIPA by failing to seek the consent of the plaintiff. The defendant filed a motion that the plaintiff was not an "aggrieved party" under sec. 20 of the BIPA because the plaintiff had not alleged an "actual injury." However, the court ruled that only the violation of the law itself is sufficient to support a private right of action under BIPA. There is no need to be actual damages of the plaintiff.

In sum, as the PDPA section 77 provides the words "causes damages to the data subject" which could be interpreted to be an injured person according to the rule of tort law which requires actual damages of an injured person. However, as the example of the rule of "aggrieved party" provided in the BIPA, the aggrieved party can sue the defendant for violating of the BIPA without concerning actual damages.

(5) Issue of compensation: The BIPA Section 20 provides that a person shall have "the right to recover each violation:"

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protection-regulation-gdpr/special-category-data/what-are-the-conditions-for-processing/#conditions1> accessed 22 May 2020.

[12] *Rosenbach v. Six Flags Entertainment Corp.,* 2019 IL 123186.

(1) “against a private entity that negligently violates a provision of this Act, liquidated damages of $1,000 or actual damages, whichever is greater;"

(2) "against a private entity that intentionally or recklessly violates a provision of this Act, liquidated damages of $5,000 or actual damages, whichever is greater;..."

There is an example case supporting this rule, that is, Brian Norberg v Shutterfly, in this case, there were many times of breaching the BIPA. Consequently, the court ruled under the BIPA section 20 that the plaintiffs had the rights to

1 "Awarding statutory damages of $5,000 for each intentional and reckless violation according to the BIPA section 20(2)."

2 "Awarding statutory damages of $1,000 for each negligent violation according to the BIPA 20(1)"

According to the study, The BIPA provides the minimum standard liquidate damages of $1,000 for negligently, and of $5,000 for each intentionally or recklessly violates the BIPA.

5. Conclusion and suggestions

From the study of the five concerning issues and solutions, this article would suggest guidance for the processing of biometric data in Thailand in practice as follows:

(1) The issue of public interest: Thailand should provide the guidelines and standard rules for the measurement of processing personal data pertaining to the public interest, by following the rules of the DPA 2018 and the ICO, that is;

1. “Determine whether an organization performs the public interest task by considering the nature of the function not the nature of the organization.”

2. “An organization that processes the personal data or Biometric data must be able to specify the relevant task and to shows a reasonable

purpose and less intrusive means to achieve that purpose. For example, a district sector must provide the reason for citizens in the collection of fingerprints. Also, It needs to choose the best way to reduce all the risks that could occur to these fingerprints information.

(2) The issue of Substantial public interest: I would suggest the following 5 required steps to process biometric data in Thailand:

Step 1: Consider the lawful basis (by following the GDPR, Article 6)

Step 2: Consider the separate 10 conditions (by following the GDPR, Article 9) in order to have more protection for the processing of special categories of personal data.

Step 3: Consider The requirement substantial public interest conditions for the processing of special category data (by following the DPA 2018, Schedule 1 part 2) in order to identify which of these conditions appears to most closely reflect his purpose.

Step 4: The controller must determine his or her conditions and have an 'appropriate policy document' in place. (by following the DPA 2018, schedule 1) because this document will demonstrate that the processing of special category data based on the rules on steps 1 – 3 above.

Step 5: Lastly, for any type of processing that is likely to be high risk, the controller needs to complete a data protection impact assessment (DPIA).

(3) The issue of explicit consent: I would suggest that Thailand should follow the guideline provided by the ICO by having the guideline of "explicit consent" in the processing of Biometric data that need to be under these 3 conditions which are;

(1) "a clear statement,"

(2) "specify the nature of the special category data,"

(3) "separate from any other consents you are seeking."

(4) The issue of civil liability: Since the words prescribed in the PDPA section 77 "causes damages to the data subject" could be interpreted to be an injured person according to the rule of tort law which requires

actual damages of an injured person. I would suggest that there should be the amendment of the PDPA by removing the word "causes damages to the data subject" so that the data subject would sue the defendant for violating of the BIPA without concerning actual damages to have the law that fully protects the Biometric data according to the purpose of the PDPA.

(5) The issue of compensation: Biometric data is considered to be a special type of data that needs to be highly protected under the PDPA, if there are many times of the violation of the PDPA, the data subject should get compensated for each violation. I suggest amending the PDPA by

1. "Adding the right to recover for each violation"

2. "Adding minimum standard liquidate damages by indicating the minimum amount of liquidated damages in each intentional and reckless violation or each negligent violation"

For example, if a shopping mall violates the law by collecting fingerprints without the consent of customers five times, the customers shall have the right to claim compensation for five violations with a minimum standard liquidate damage for example 10,000 baht for each violation.

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CORPORATE CRIMINAL LIABILITY FOR BRIBERY OFFENCES IN PRIVATE SECTOR*

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Abstract

Corruption has long been recognised as a significant problem in all countries, with bribery being a form of corruption that is likely to occur on a daily basis. Both public and private bribery have a widespread effect on a country in terms of harming economic growth and creating social inequality.

Although the number of private-to-private bribery cases has significantly increased due to changes in the world's social context, according to the study, no direct legal provision has been regulated to control bribery in Thailand's private sector. The current Thai bribery laws are focused on public bribery, including the bribery of foreign public officials, and are unable to be adapted for use with general cases of private bribery.

This article would like to propose the criminalisation of private-to-private bribery by both individuals and juristic persons and regulating the offence of private bribery under the Thai Penal Code.

Keywords: Bribery, Corruption, Bribery in Private Sector

* This article is summarised and rearranged from the thesis "Corporate Criminal Liability for Bribery Offences in Private Sector", Faculty of Law, Thammasat University, 2019.

1. Introduction

Corruption is a significant problem that hinders countries' economic growth on a global scale. It is a particularly endemic problem in Thailand, where the population is generally of the opinion that it is traditional to pay a bribe in exchange for favours. This is confirmed by Thailand ranking 101st of 180 countries listed in the Corruption Perceptions Index (CPI) 2019 announced by Transparency International, with a score of 36 points out of a total of 100.[1] It is common in Thailand for individuals or private companies to bribe public officials, and the existing Thai anti-bribery law is only focused on bribery in the public sector. There is no direct legal provisions regarding bribery in the private sector.

Although private-to-private bribery does not involve public officials, it still has a widespread effect on the public order by causing unfair trade competition across the market, which leads to economic concentration and eventually, social inequality. Transparency International (TI) is also of the view that 'private sector corruption should be subject to preventative measures and should be criminalised just like corruption in the public sector. The private sector has become larger than the public sector in many countries and the line between the two sectors is blurred by privatisation, outsourcing and other development.'[2]

The private sector has grown to play a significant role in the economy of many countries, and Thailand is no exception. In order to create an anti-corruption environment, build and maintain fair trade competition in the Thai market and obtain the trust of foreign investors, the Thai anti-bribery law should focus on the laws that control bribery in the

[1] Transparency International, 'Corruption Perception Index 2019' (*Transparency International*) <https://www.transparency.org/en/cpi/2019/results> accessed 20 June 2020.

[2] Transparency International, 'UN Convention Must Criminalise Private Sector Corruption' (*Transparency International*, 10 march 2003) <https://www.transparency.org/en/press/un-convention-must-criminalise-private-sector-corruption-says-transparency#> accessed 7 June 2020.

private sector, as well as in the public one. If Thailand can control, or ideally prevent, bribery in the private sector as well as the bribery in the public sector, it will create a less corrupt environment in which it will gain foreign investors' trust and hence, the necessary funding for development. This will help to improve the employment rate and the distribution of income, thereby achieving sustainable social equality.

2. Bribery in the Private Sector and Corporate Criminal Liability

There is no one universal definition of bribery, since the meaning can vary based on the socio-economic, political and cultural factors of each country. However, bribery could be summarised as meaning to offer, promise, give or accept an asset or other advantage in exchange for something in return or to induce another person to do or not to do something illegal for the benefit of the bribe giver or a third party.

In this regard, bribery could be separated into 1.) Active Bribery is the case where a person offer, promise, or give a bribe to other persons in exchange for a benefit to themselves or other. 2.) Passive Bribery which occurs when persons request, accept, or receive a bribe.[3] Hence, to control or, ideally, prevent bribery in the private sector, the domestic law should cover both cases where juridical persons act as bribe givers or bribe receivers.

2.1 Bribery in the Private Sector

Private-to-private bribery is defined as bribery from a business operator to an entity or individual of a counterparty.[4] A classic example of private-to-private bribery is when sales persons or company managers give or promise to give money, presents or other benefits to buyers of other

[3] Transparency International UK, 'Global Anti-Bribery Guidance' (*Transparency International UK*) <https://www.antibriberyguidance.org/guidance/5-what-bribery/guidance> accessed 25 May 2020.

[4] Jeffrey R Boles, 'The Two Faces of Bribery : International Corruption Pathways Meet Conflicting Legislative Regimes' (2014) 35(4) Michigan Journal of International Law 673.

companies to induce them to purchase their products or to secure an order. In these cases, the payment of the bribe may be to benefit the buying company or the sales persons by helping them to meet their sales target, or to benefit both sides.[5] Because private-to-private bribery can benefit both sides (the bribe giver and bribe receiver), there is very little information of actual cases of private-to-private bribery in the public domain.

However, Singapore, the only Asian country who ranked in the top 10 of the Corruption Perception Index produced by Transparency International, published that in the last 5 years the number of corruption in private sector continue to be the majority of all the corruption cases registered for an investigation (85-90% of the total cases registered for an investigation).[6] Thus, this number would be similar to other countries where the number of private bribery are growing continuously.

The consequence of private-to-private bribery affects both of private sector itself and to public sector. For private part, bribery creates unfair competition because not all companies are able to pay a bribe. While some are both able and willing to pay a bribe in exchange for some advantages, others in the market that may not be able to do so may be excluded from market competition.[7] Private bribery could impact through the whole supply chain, distorting markets and competition.

The legal treatment of private-to-private bribery differs among countries based on the value of the bribe. However, the major response is

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[5] Antonio Argandoña, 'Private-to-Private Corruption' (2003) 47(3) Journal of Business Ethics 253.

[6] Corrupt Practices Investigation Bureau, 'Corruption Situation In Singapore Remains Firmly Under Control' (*CPIB*, 18 May 2020) <https://www.cpib.gov.sg/press-room/press-releases/corruption-situation-singapore-remains-firmly-under-control?> accessed 1 June 2020.

[7] United Nations Office on Drug and Crime, 'Consequence of Private Sector Corruption' (*UNODC*, December 2019) <https://www.unodc.org/e4j/en/anti-corruption/module-5/key-issues/consequences-of-private-sector-corruption.html> accessed 29 May 2020.

to criminalise it.[8] To effectively enforce the criminal offence of private bribery, each country needs to clearly define the scope and definition of 'corporate liability' because, since private bribery can be done for the benefit of the private company itself, it should also be penalised.

2.2 Corporate Criminal Liability and Sanctions

According to Article 59 of the Thai Penal Code, persons shall be liable for a criminal offence when they commit an act intentionally. However, when considering corporate criminal liability, there is a need to determine if a juristic person who is a person established under the law could act with the intention and criminalise. The Thai criminal law has adopted the identification doctrine as a model of the criminalisation of corporate criminal liability. Under the identification doctrine model, the determination of corporate criminal liability depends on connecting the juristic person to its directing mind (i.e. director or representative), who acts in the scope of the juristic person's objective and for its benefit.

Regarding the criminal sanctions, in Thailand, according to Section 18 of the Thai Penal Code, the punishments that can be imposed on offenders consist of death, imprisonment, confinement, fines and the forfeiture of property. All these criminal sanctions can be imposed on a natural person, but only fines and the forfeiture of property can be imposed on juristic persons due to their nature.

2.3 The Current Thai Law in relation to Bribery

As mentioned earlier, there is no direct legal provision in Thailand related to bribery in the private sector. However, there are provisions that could probably be adapted for use with private bribery cases under Section 353 of the Thai Penal Code, Section 176 of the OACC and Section 57 of the

[8] United Nations Office on Drug and Crime, 'Response to Private Sector Corruption' (*UNODC*, December 2019) <https://www.unodc.org/e4j/en/anti-corruption/module-5/key-issues/responses-to-private-sector-corruption.html> accessed 28 May 2020.

Trade Competition Act B.E. 2560 – Unfair Trade Practices, which are detailed below.

2.3.1 Section 353 of the Thai Penal Code: Dishonest Actions Contrary to One's Duty

Although Thailand has no direct legal provision related to bribery in the private sector, Section 353 of the Thai Penal Code could be adapted for use in specific bribery cases.

The offence is committed when a person who is entrusted to manage another person's property 'destroys trust' by dishonestly performing any act contrary to his/her duty and such act damages the benefit of the other person's property.[9] The duty under this provision could be a duty established by law, such as a legal representative, a duty established in a contract, such as the branch manager of a bank, or a court-appointed duty, such as heritage administrator.[10] This provision requires both general and specific intent. The specific intent required under this provision is dishonesty, which involves seeking any kind of undue benefit, such as the membership of a golf club, promotion, or the right to school admission, etc. Therefore, in my opinion, this provision could be applied to bribery in the private sector if it was committed by an agent, employee or another person appointed by the company whose duty was established in a contract, but there needs to be proof that the action damaged the company's property.

Nevertheless, although Section 353 of the Thai Penal Code can be applied to bribery in the private sector in some specific cases, it is limited by the need for the property owner to prove that his benefits had been damaged by the bribery. Therefore, in my opinion, this provision cannot be

[9] Kanaphon Chanhom, *Kham Atibai Kotmai Arya Pakkwampid Lem 3* [*The Explanation of Criminal Law, Misconducts Part Book 3*] (5th edn, Winyuchon 2020) 378 (คณพล จันทน์หอม, *คำอธิบายกฎหมายอาญาภาคความผิด เล่ม 3* (พิมพ์ครั้งที่ 5, วิญญูชน 2563) 378.

[10] ibid.

applied to general bribery cases, since not every general bribery case causes damage to property.

2.3.2 Article 176 of the Organic Act on Counter Corruption B.E. 2561

According to Article 176 of the OACC, it is a criminal offence for individuals and juristic persons to bribe a public official, foreign public official or an official of a public international organisation. This provision is consistent with the mandatory requirement in Articles 15 and 16 of the UNCAC with regard to the bribery of national public officials, foreign public officials and officials of public international organisations.

Article 176 imposes the concept of corporate criminal liability for the offence of bribery if the person doing the bribing is associated with a juristic person and committing the bribery for its benefit and the juristic person shall be liable for a criminal offence under this Article if it has failed to implement an appropriate internal control to prevent that person from committing the bribery. A person associated with a juristic person can be its representative, employee, agent, its affiliate company, or any person who acts on its behalf, regardless of whether they have the power or the authority to perform such action.[11]

Although this provision regulates private-to-public bribery, some parts of it can be used to address private-to-private bribery when drawing on anti-bribery law. Nevertheless, this provision is limited in that it only penalises active bribery in the public sector; therefore, passive bribery and the object of the criminal action need to be considered in order to adapt this provision for use with private-to-private bribery.

[11] Office of the National Anti-Corruption Commission, Organic Act on Counter Corruption B.E. 2561 (2018) s 176.

2.3.3 Article 57 of the Trade Competition Act B.E. 2560 – Unfair Trade Practices

As mentioned earlier regarding the impact of private bribery, it creates unfair competition, since not all companies in the market are willing or able to pay a bribe. Therefore, the Trade Competition Act B.E. 2560 was enacted in Thailand to prevent unfair trade. It is stated in Article 57 that a business operator should not behave in a way that damages other operators by unfairly restricting their business, unfairly using superior marketing power or bargaining power, or unfairly defining trade conditions to limit or restrict another operator's business.

This is a broad provision, since there is a need to consider what constitutes the 'damage' one business operator could cause to another. According to the guidelines provided by the Office of Trade Competition Commission (OTCC), the consideration of a wrongful act under Article 57 of the Trade Competition Act B.E. 2560 that can damage another business operator should be based on economic loss, such as the loss of income of the business operator, loss of the market value of goods or services and loss of production or the provision of a service opportunity.[12] If adapting this provision to determine if private bribery causes unfair competition, it is difficult to prove the 'damage' incurred by the other business operator. Hence, the burden of proof of 'damage' rests with the judge.

Apart from proof of damage, the OTCC also provides guidelines to prove an 'unfair act'. This is an act that is not normally performed during the course of business, the conditions are not in writing and the other business operator is not informed of it in advance within a reasonable period according to trade tradition, and such an act is not reasonable based on business morals, marketing or economic.[13] In this context, it is difficult to

[12] Office of Trade Competition Commission Notification on the Guideline to Considerate the Damages Causes to Other Business Operators B.E. 2561 (2018) art 5.

[13] ibid, art 11.

prove if an act was unfair, as well as if it damaged the other business operator.

In view of the above, it appears to be difficult and time-consuming to prove a wrongful act under Article 57 of the Trade Competition Act B.E. 2561. Therefore, it may not be suitable to adapt to use with private bribery.

3. International Treaty and Foreign Countries' Anti-Bribery Law in the Private Sector

Regarding that the current Thai law in relation to bribery may not be used for general private bribery cases, the concept of the anti-bribery law that applies to the private sector of the UNCAC, Singapore, UK and German law will be examined in order to identify an appropriate legal model that can be adapted for use with Thai law.

3.1 United Nations Convention against Corruption 2003 (UNCAC)

The United Nations Convention against Corruption 2003 was the first universal anti-corruption instrument adopted at the United Nations General Assembly on the 31st October 2003 and it came into force on the 14th December 2005. 187 countries had become party to the UNCAC as of the 6th February 2020,[14] with 140 signatory countries. Thailand signed the Convention on the 9th December 2003 and ratified it on the 1st March 2011.

Article 21 of the UNCAC contains an optional requirement for each State Party to consider enacting and implementing legislation and other measures to criminalise bribery in the private sector if it was committed intentionally during the course of economic, financial or commercial activities. This criminal offence covers the direct or indirect act of a promise, offer, gift, request or acceptance of an 'undue advantage' that causes

[14] United Nations Office on Drug and Crime, 'United Nations Convention against Corruption' (*UNDOC*) <https://www.unodc.org/unodc/en/corruption/uncac.html> accessed 3 June 2020.

persons who work for a company in the private sector or for themselves to breach their duty. [15]

3.2 The Prevention of Corruption Act of Singapore

Singapore has the distinction of being the least corrupt country in Asia based on the Corruption Perception Index (CPI) 2019 produced by Transparency International. In the global coalition against corruption, Singapore was ranked 4th of 180 countries with a score of 85 of 100[16] (Denmark was ranked 1st with a score of 87. A score of 100 means no corruption). Singapore is the only Asian country in the top 10 of the CPI.

Singapore signed the UNCAC on the 11th November 2005 and then ratified it on the 6th November 2009. The Prevention of Corruption Act (PCA) was enacted on the 17th June 1960, Chapter 241 of the PCA, which is the major anti-corruption legislation in Singapore, criminalises bribery in both the private and public sectors and provides a clear and broad definition of 'gratification' which, in summary, includes both monetary and non-monetary, tangible and intangible benefits. Bribers and those being bribed under the PCA could be both individuals and corporations, whether the offence was committed directly or indirectly.

The PCA also clearly empowers Corrupt Practices Investigation Bureau (CPIB) to make an arrest and investigate cases of corruption, which enables them to work independently with the full authorisation to deal with all corruption cases in Singapore. Furthermore, it contains a clear provision to protect informers in corruption cases, which is the key to fighting corruption, especially in the private sector, where both the bribe giver and bribe receiver benefit from the corruption. In these cases the

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[15] United Nations Convention against Corruption (adopted 31 October 2003, entered into force 14 December 2005) A/58/422, art 21.

[16] Transparency International, 'Corruption Perceptions Index Singapore' (*Transparency International*) <https://www.transparency.org/en/cpi/2019/results/sgp> accessed 30 May 2020.

corruption would be unlikely to be revealed without the aid of a whistle-blower.

3.3 The Bribery Act 2010 of the United Kingdom

In order to combat bribery, the Bribery Act 2010 (UK Bribery Act) came into force on the 1st July 2011. The UK Bribery Act is a regulation that criminalises bribery in both the public and private sectors. The UK Bribery Act contains a clear definition of bribery and introduces a strict liability offence for the failure of companies and partnerships to prevent the offence of bribery from being committed by persons associated with them under Article 7 of the UK Bribery Act. However, the UK Bribery Act provides a defence for the relevant commercial organisation if it can prove that it has put 'adequate procedures' in place to prevent its associated person from committing the offence of bribery.

The focus on private sector bribery and the strict liability for commercial organisations to prevent bribery distinguishes the UK Bribery Act from any previous regulations.

3.4 The Anti-Bribery Law of Germany

According to the CPI, Germany ranked 9th of 180 countries in 2019 with a score of 80 out of 100.[17] The anti-bribery law in Germany covers bribery in the public, as well as the private sector. Bribery committed by an individual in the private sector is regulated under the German Criminal Code (Strafgesetzbuch – StGB). However, bribery that involves a legal person will be penalised under the Act on Regulatory Offences (Gesetz über Ordnungswidrigkeiten - OWiG), since Germany has no concept of corporate criminal liability. Regarding that there is no specific authorisation for the offence of bribery in Germany, the public prosecutors' office is responsible

[17] Transparency International, 'Corruption Perception Index Germany' (*Transparency International*) <https://www.transparency.org/en/countries/germany> accessed 24 July 2020.

for investigating the private bribery committed by an individual, which is criminalised under the German Criminal Code.[18] Meanwhile, the Administrative Authority is empowered to investigate private bribery that involves a legal person by the Act on Regulatory Offences.

However, the Federal Ministry of Justice and Consumer Protection (BMJV) published a draft bill in April 2020 in relation to corporate criminal liability entitled the 'Corporate Liability Act (Verbandssanktionengesetz : VerSanG)'.[19] This draft bill introduced a corporate crime which involves an action that violates the obligations of the company or one that results in enriching the company.[20]

4. Comparative Analysis of the Offence of Private-to-Private Bribery under the Singaporean, UK, German Laws and Article 21 of the UNCAC

The concept of the anti-bribery law in the private sector under the UNCAC, the UK bribery Act and the PCA criminalises both active and passive bribery committed by either a natural person or a juristic person. The German law also criminalises active and passive bribery in the private sector committed by a natural person and the legal person is also liable for an administrative fine if it is involved in bribery in the private sector. However, the private bribery offence in Germany is more specific and narrow than in the UNCAC, the UK bribery Act and the PCA, since it is limited to the

[18] Global Legal Insights, 'Bribery & Corruption 2020 | Germany' (*Global Legal Insights*) <https://www.globallegalinsights.com/practice-areas/bribery-and-corruption-laws-and-regulations/germany> accessed 9 September 2020.

[19] Nicolai Behr and Robin Haas, 'German Ministry of Justice publishes draft corporate liability act – what companies must expect' (*Verbands Sanktionen Gesetz*, 26 April 2020) <https://verbandssanktionengesetz.de/german-corporate-liability-act-20200426/> accessed 9 September 2020.

[20] Nicolai Behr, 'Section 2 – Definition; offences committed aboard' (*Verbands Sanktionen Gesetz*, 5 May 2020) < https://verbandssanktionengesetz.de/chapter/section-2-definitions-offences-committed-abroad/> accessed 9 September 2020.

objective of a competitive purchase of goods or services and does not cover other aspects of private bribery.

The definition of a bribe is also broad, since it can be a monetary, non-monetary, tangible or intangible benefit paid to induce or reward any person for breaching his or her duty.

In terms of corporate criminal liability for the offence of bribery in the private sector, the UK Bribery Act includes the concept of strict liability for commercial organisations where the commercial organisation could fall under the private bribery offence for failing to prevent persons associated with them from committing the offence. This strict liability of a juristic person can also be found under the Act on Regulatory offences of Germany if the legal person's representative or executive committed the bribery offence by violating the juristic person's duties, or if the legal person failed to prevent or make it difficult for its staff to commit the offence. The concept of strict liability is suitable for use with a juristic person, since it does not require proof of intent.

Furthermore, in Singapore, the PCA contains a clear provision to protect informers in corruption cases, which is key to fighting corruption, especially in the private sector, where both the bribe giver and bribe receiver benefit from the corruption. In these cases the corruption would be unlikely to be revealed without the aid of a whistle-blower. Moreover, in Singapore, it is easy for the public to access the CPIB. They can report instances of corruption by writing to the CPIB, calling the duty office, issuing an e-complaint via the CPIB website or e-mail and, if the complaint contains sufficient information and falls within the remit of the CPIB, it will investigate it and take further action if needed.

In terms of territorial reach, I would like to highlight the broad extra-territorial effect of the UK Bribery Act. The benefit of the UK bribery act is the territorial reach of corporate criminal liability for failure to prevent bribery, which covers 1) a company that is incorporated under UK law, and 2) a company that is incorporated anywhere, which is operating a business or part of a business in the UK, regardless of the acts or omissions that form

part of the related offence. This enables the UK government to control all companies that operate in the UK, as well as UK companies that operate in other countries around the world.

5. Conclusion

To successfully combat corruption in Thailand, it is important to regulate legislation related to bribery in the private sector. Since there is no other measure to enforce the law or compel people to comply with it, the offence of bribery in the private sector should be criminalised in order to deter people from committing it. Based on the study of the UNCAC, the UK Bribery Act, the PCA and German Criminal law, Thailand should legislate bribery in the private sector under the Thai Penal Code as an offence covering both active and passive bribery committed directly or indirectly by either a natural person or a juristic person. In addition, since private companies play a significant role as bribe givers, Thailand should also adopt the strict corporate liability of the UK's bribery act by imposing strict liability on private companies that fail to prevent bribery from being committed by an associated person. Furthermore, the sanctions should be proportionate to the offence; therefore, the penalty imposed should at least cover the amount of the bribe. In addition, the government should enact a law to protect informers in order to give them confidence to come forward and encourage society to help to monitor bribery in the private sector in Thailand.

Although criminal law may be used as an instrument to deter bribery and protect the public order, criminal law on its own is inadequate to combat corruption. In the longer term, it is important to educate the Thai people to see the big picture and be aware of the negative consequences of this offence, even on a small scale, so that Thailand will eventually become a country that has zero-tolerance of the corruption that is currently harming its economic development.

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SAFETY MEASURES FOR MEDICINAL PRODUCTS*

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Abstract

This article explores the problems on safety measures for medicinal products in Thailand, which is a major problem in Thailand because there are plenty of defective medicinal products causing injuries to consumers in Thailand. The existing safety measures for medicinal products, in practice, are ineffective to protect the consumer from unsafe products and lead to the continuously raising of defective medicinal products on the market.

This article applies a comparative study to examine how other countries i.e. the European Union, the United States, and Singapore solve the problem. Therefore, this article explores the provisions regarding safety measures for medicinal products of the EU Directive 2001/83/EC, the US Code of Federal Regulations (CFR), and the Singapore Health Products (Therapeutic Products) Regulations 2016 in order to find a recommendation for Thailand.

From the comparative study, this article proposes that the provisions concerning safety measures for medicinal products under Thai Drug Act of B.E.2510 (1967) (as amended in 2019), the validity of drug registration, re-evaluation measure before distribution, monitoring, and safety alert on dangerous medicinal products should be amended.

Keywords: Medicinal Products, Safety Measures, Product Safety Law

* This article is summarised and rearranged from the thesis "Safety Measures for Medicinal Products" Faculty of Law, Thammasat University, 2019.

1. Introduction

Medicinal products are substances intended for use in the diagnosis, cure, or prevention of human or animal disease.[1] However, this article only focuses on medicinal products designed for use in humans, not include animals. Unlike other general products, medicinal products are considered as unavoidably unsafe products because they have particular characteristics and even appropriately administered, their side effects may be harmful to the consumer, so it is important to prevent the occurrence of adverse effects and guarantee safety of medicinal products.

There is legislation governing safety measures for medicinal products that are applied in the European Union,[2] the United States,[3] and Singapore[4] where there are distinctive legal approaches in resolving medicinal product problems. These safety measures for medicinal products cover in all parts of the medicinal product's lifecycle, initiate from the manufacturing, clinical trial, marketing authorization, distribution, to pharmacovigilance. The main goal is to support medicinal products to meet three criteria of quality, safety, and efficacy.[5]

Thailand has legal protection both general and specific for product safety. Consumer Protection Act of B.E. 2522 is the general product safety law that protects the fundamental rights of consumers in general and only applies to the general consuming products.[6] Meanwhile, the drug is the special product governed by other laws, namely Drug Act of B.E. 2510 (1967)

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[1] Drug Act of B.E.2510 (1967) (as amended in 2019) s 4.

[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

[3] Code of Federal Regulations (CFR).

[4] Health Products (Therapeutic Products) Regulations 2016.

[5] Nuala Calnan, 'Overview of the recent FDA Process Validation Guidance for Medicinal Product Development and Manufacture' (PDA Ireland Symposium: Embracing the Challenges of Lifecycle Based Validation, 7 June 2013).

[6] Susom Supanit, *Commentary on Consumer Protection Laws* (8th edn, Chulalongkorn University 2014).

(as amended in 2019) – Thai Drug Act, which shall apply the Consumer Protection Act as long as it does not contrary to such provision. Although the Thai Drug Act imposes safety measures for drug in several aspects of registration, labelling, advertising, monitoring, and enforcement, the problems relevant to the drug are continuously raised because current safety measures are not comprehensive and effective as preventive measures to protect the consumer and prevent the injuries from a defective drug.

2. Development of safety measures for medicinal products

In Thailand, the private law imposes product liability as a remedial measure, but it does not prevent dangerous products from being placed on the market, so defective medicinal products are continuously rising. Besides, the development of establishing safety measures for medicinal products has the characteristic to enacts the public law to dominate the private law and cannot set up preventive measures. Therefore, there is a need for establishing preventive measures to protect consumer. To understand the necessity and importance of preventive measures for medicinal products, this part explores the development of safety measures for medicinal products by explaining and comparing product liability on medicinal products with medicinal products safety.

2.1 Product liability on medicinal products

It is essential that when a product causes damage to consumers, preventive measures are proceeded to prevent or avoid such products be available in the market. However, the private law enforced at that time mainly focuses only on correcting harm and injuries that occurred and providing compensation. Private law only addresses the problem and compensates after the injury occurred. Besides, private law does not directly prevent harmful products to market circulation and to prevent damage from occurring.

Meanwhile, the safety of the products is the essential goal of product safety measures to protect the consumer. Hence, product safety systems are designed as a preventive measure to protect unsafe products from accessing the market or the consumer. It is insufficient for preventing injury even though producers design, manufacture and sell products by intended to be safe. The method of use may also affect the safety of the product.

Therefore, there is a need for preventive measures relevant to certain controls to protect the consumer, which prevents dangerous products from reaching the market, along with providing post-marketing measures such as monitoring and surveillance.

2.2 Medicinal products safety

Product safety laws are preventive measures taking unsafe products away from the markets. In the case of medicinal products which fall within specific guidelines to qualify as an "unavoidably unsafe products" because although a product is cautiously designed, produced, and marketed, it is still hazardous. Moreover, the use of medicinal products associated with some injuries because they are hazardous products and have a pharmacological effect.[7] The higher risk, the more serious action should be taken, particularly medicinal products are more complex and must have the appropriate and effective measures to guarantee the safety of the medicinal products.

Consequently, medicinal product safety was considered to separate from the general product safety and have an explicit requirement that is covered by specific legislation, namely medicinal product safety provisions. Furthermore, the safety evaluation of the products is taken at pre-marketing stage is merely provisional and must be continuously reassessed throughout

[7] Natthaphon Chaichatchawan, 'Kotmai Waduay Khwamplotphai Khong Sinkha [Product Safety Law]' (Masters of Laws Thesis, Thammasat University 2013) (ณัฐพร ชัยชัชวาล, 'กฎหมายว่าด้วยความปลอดภัยของสินค้า' (วิทยานิพนธ์ปริญญามหาบัณฑิต, มหาวิทยาลัยธรรมศาสตร์ 2556)).

the lifetime of marketing the product. For the entire duration of medicinal products' lifetime, continued safety surveillance is required to discover adverse reactions, to constantly reassess the safety profile through a re-assessment of benefit-risk ratio of the product, and to attempt to quantify the risk to the patient.

3. Analysis of safety measures for medicinal products

This part analyzes the problems on safety measures for medicinal products in Thailand. The analysis is based on the comparative study of the law of the European Union, the United States, and Singapore to explore effective safety measures for medicinal products in Thailand. From the study of Thai Drug Act concerning safety measures for medicinal products, there are problems on product safety measures for medicinal products as follow:

3.1 The inappropriateness of safety measures relevant to the renewal of the marketing authorization

3.1.1 The flaw of the validity of drug registration

The Thai Drug Act regulates that "The drug registration certificate will be valid for seven years from the date of issue."[8] This demonstrates that the period of the validity of drug registration is too long. As a result, the assessment of medicinal products at the time of application for renewal of drug registration will be delayed. Besides, there is no evaluation of medicinal products to identify defects, reassess the safety, and recheck whether a product placed on the market is safe. Therefore, a long period of validity of drug registration shall increase the risk of defective products in the market circulation and the consumer may be harmed before the assessment is performed.

[8] Drug Act of B.E.2510 (as amended in 2019) s 86/2 para 1.

Meanwhile, the EU regulates the validity of a marketing authorization for five years, which is an appropriate period to reassess products after launching to the market because if the period is too short, it will increase the burden to authority or responsible person to assess products frequently. By taking the EU as a model law, Thai Drug Act should be revised by amending the period of validity of drug registration from seven years to five years from the date of issue.[9]

Therefore, the author recommends that Section 86/2 paragraph 1 should be amended as "The drug registration certificate will be valid for five years from the date of issue. In the event where there is a reason to suspect the danger of medicinal products, competent authorities have the power to prescribe a period of the validity of drug registration shorter than five years from the date of issue."

3.1.2 The absence of the review of drug formula upon the renewal application

In the process of application for renewal of the marketing authorization, Thai Drug Act regulates that "The renewal of drug registration certificate shall conform to the Ministerial Regulation and such Ministerial Regulation may be prescribing the review of drug formulas."[10] This demonstrates that Ministerial Regulation may prescribe the application for the renewal of the marketing authorization without the review of drug formulas, so there is no certainty to review drug formulas because the review of drug formulas depends on whether the Ministerial Regulation prescribes to perform. As a result, information relevant to medicinal products shall not be updated as it should be, and it will increase the risk of injuries from unsafe medicinal products on the market.

However, the drug formulas should be monitored and revised periodically to ensure maintaining the quality of medicinal products.

[9] Christopher Hodge, *European Regulation of Consumer Product Safety* (OUP 2005).

[10] Drug Act of B.E.2510 (as amended in 2019) s 86/2 para 5.

Likewise, the EU and the U.S. both require the revision of the drug formulas periodically to update the information relevant to medicinal products and ensure the quality of medicinal products. Therefore, the author recommends that Section 86/2 paragraph 5 should be amended by adding "The renewal of drug registration certificate shall be compliance with the rule, conditions, and procedures prescribed in the Ministerial Regulation. Before the renewal of marketing authorization, the drug formula must be reviewed."

3.2 An absence of safety measures before distribution

After the authorization process, whether the manufacturing of medicinal products complies with the authorized specification is unknown. Medicinal products change hands many times between the manufacturer and consumer; so there is a risk of medicinal products to become dangerous in every transaction. Moreover, the danger of medicinal products may not occur at the time of authorization but may present inherent risks after the first testing or clinical trials. Thus, the way risks will be minimized once medicinal products are reassessed before distribution. The purpose of the re-evaluation of medicinal products is to confirm and discover the side-effects of the tested medicinal products in order to prove their safety or efficacy in human use.

Thai Drug Act does not regulate the provision regarding the repeated testing of medicinal products before distribution. Meanwhile, the U.S. establishes the release testing to test medicinal products before distribution and ensure the compliance of medicinal products with their granted specification.[11] Therefore, by taking the U.S. as a model law, Thai Drug Act should be amended by adding the provision regarding the re-evaluation measure for approved medicinal products. Furthermore, the licensee should

[11] U.S. Food and Drug Administration, 'The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective' (*FDA*, 24 November 2017) <https://www.fda.gov/drugs/drug-information-consumers/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective> accessed 10 July 2019.

be responsible for submitting a benefit-risk evaluation report to the Food and Drug Administration – FDA, before releasing medicinal products to the market.

Therefore, the author recommends that Thai Drug Act should be amended by adding Section 26/1 "Before distribution of medicinal products, licensee to sell must submit a benefit-risk evaluation report to the Food and Drug Administration."

3.3 An absence of monitoring measures by the licensee

Although Thai Drug Act prescribes the rules for monitoring obligations to supervise medicinal products, the Act only empowers the competent authorities to monitor drug and enter the premises for the production, sale, importation of storage of drug, take reasonable quantities of drug as samples for testing or analysis, size or attach drug and equipment concerned with offense.[12] Meanwhile, the licensees and all persons involved such products are liable to provide reasonable facilities when the competent authorities perform their duties.[13]

Furthermore, in the case that the competent officials know that any drug may be dangerous to the consumers, the competent authorities are authorized to recall dangerous products and to order licensee to produce, sell, or import to recall their products from the market[14] and sent to the FDA within 15 days if the product has been found to cause serious health problems or within 30 days if the product is suspected of causing severe

[12] Drug Act of B.E.2510 (as amended in 2019) s 91(1)-(4).

[13] ibid, s 91 para 2.

[14] ibid, s 91(5).

health problems.[15] Besides, the competent authorities are empowered to destroy such products.[16]

These provisions under Thai Drug Act as mentioned above demonstrate that there is an absence of monitoring measures by the licensee because the Thai Drug Act does not require the licensee to recall suspected dangerous products from the market. Besides, the existing rules do not provide adequate protection against defective medicinal products. Meanwhile, the EU and Singapore require the licensee to provide information relevant to their products, collect the sample of the product for conducting quality testing, and periodical report an assessment of the risk-benefit balance in order to reduce the risk of dangerous product and assure the quality of products placed on the market.[17] Therefore, by taking the EU and Singapore as a model law, Thai Drug Act should be amended by adding the provision regarding monitoring obligation for the licensee to monitor their medicinal products placed on the market by sampling and reporting the result of sampling to the competent authorities every year. The reporting must contain the sampling of medicinal products with the minimum information covering the name of the product, dosage form, indications, an adverse effect, place, and date of practice, and the result of sampling. In the case of danger, the licensee shall voluntarily recall defective medicinal products or ordered by competent authorities to

[15] Kod Krasuang Chabub Tee 20 (Por Sor 2525) Ork Tarm Kwam Nai Pra Ratchabunyat Ya Por Sor 2510 [Ministerial Regulation No. 20 B.E. 2525 (1982) Issued under the Provisions of Drug Act B.E.2510 (1967)] (กฎกระทรวง ฉบับที่ 20 (พ.ศ. 2525) ออกตามความในพระราชบัญญัติยา พ.ศ. 2510).

[16] Sutthinee Borisuttham, 'Mattrakan Riekkheun Sinkha Pheua Kan Khumkhrong Phuboriphok [The Consumer Protection : Product Recall]' (Master of Laws Thesis, Thammasat University 2011) (สุทธินี บริสุทธิ์ธรรม, 'มาตรการเรียกคืนสินค้าเพื่อการคุ้มครองผู้บริโภค' (วิทยานิพนธ์มหาบัณฑิต, คณะนิติศาสตร์ มหาวิทยาลัยธรรมศาสตร์ 2554)).

[17] Directive 2001/83/EC, art 104, 211.110(a) and Health Products (Therapeutic Products) Regulations 2016, regulation 34.

remove a defective product from the market, and the FDA withdraw such products from the market.

Therefore, the author recommends that Thai Drug Act should be amended by adding Section 26/2 "Licensee to sell shall monitor medicinal products placed on the market by yearly sampling and reporting the result of sampling to the competent authorities. The reporting shall consist of the sampling of medicinal products covering the name of the product, dosage form, indications, an adverse effect, place, and date of practice, and the result of sampling. In the case of danger, the licensee shall voluntarily recall defective medicinal products or ordered by competent authorities to remove a defective product from the market, and the Food and Drug Administration shall withdraw such products from the market."

3.4 The ineffectiveness of safety alert measures on dangerous medicinal products

Thailand established a pharmacovigilance center, the Health Product Vigilance Center (HPVC), to monitor and collect the Adverse Drug Reactions - ADRs reporting of health products, detect signals and assess ADRs in order to identify the product safety problem, and then collaborate the ADRs data with the local and international levels. The scope of health products covers medicinal products, narcotics and psychotropic substances, foods, cosmetics, medical devices, and hazardous substances.[18] The FDA has issued The Announcement regarding the guidance for Market Authorization Holders -MAHs on post-marketing safety reporting to provide a guide for MAHs to submit health products safety reports to HPVC.[19] The MAHs are required to

[18] Health Product Vigilance Center, 'The Statistics of the HPVC Reporting of All Suspected Adverse Events of the Health Products in 1984-2019 (September)' (*Thai FDA*, 10 November 2019) <http://thaihpvc.fda.moph.go.th/thaihvc/Public/News/uploads/hpvc_5_13_0_100805.pdf> accessed on 11 October 2019.

[19] The Announcement of Food and Drug Administration: The guidance for marketing authorization holders on post-marketing safety reporting for human drugs, narcotics, and medicinal neurophychotropic substances, dated 18 December 2015.

submit health product safety reports to Thai Vigibase, developed by the HPVC, which is a national database that collects reports of health products. Although the responsible person to report is the MAHs of health products, the majority of reports submitted to HPVC are voluntarily reported by governmental hospitals, drug stores, and healthcare professionals.[20]

There are problems on the ineffectiveness of safety alert measures on dangerous medicinal products. The reporting of ADRs is a vital system for the detection of defective medicinal products, but the ADRs reporting is not regulated under the Thai Drug Act, which is specific legislation governing medicinal products in Thailand. The FDA only issued "The Announcement entitled the guidance for MAHs on post-marketing safety reporting". The legal status of the guidance on post-marketing safety reporting lack of effective enforcement and lead to ineffectiveness of the reporting in practice. As a result, the HPVC received reports of adverse events of health products that occurred in Thailand less than was actually received. Therefore, to regulate the reporting measure to be enforceable in practice, the ADRs reporting should be imposed under Thai Drug Act.

The scope of health products required for submitting ADRs reports to the HPVC covers the wide range of health products. The identification of the product safety problem from the various product reports leads to confusion and wasting time to categorize the type of products before the assessment and cause the delay of the evaluation to decide to take further regulatory action. Moreover, medicinal products are unavoidably unsafe products, so they should be taken appropriate action abruptly when an adverse event occurs. Therefore, a pharmacovigilance center for medicinal products should be separated from other health products to emphasize more on the problem regarding medicinal products in order to effectively assess the ADRs reports, take directly and appropriate actions to resolve

[20] Wimon Suwankesawong, 'Pharmacovigilance in Thailand' (*HPVC*) <https://www.genome.gov/Multimedia/Slides/SJS_TEN2015/12_Sewankesawong.pdf> accessed 11 October 2019.

with the safety problem of medicinal products, and communicate ADRs reports to relevant parties and foreign countries readily.

Moreover, the guidance imposed The MAHs as the responsible person; in fact, they submitted a few ADRs reports. Meanwhile, healthcare professionals, hospitals, and consumers should be required to submit the ADR reports because they are an essential part of the treatment team, especially when an ADRs occurs, and can contribute more safety data related to medicinal products. Moreover, the majority of ADR reports submitted by healthcare professionals, hospitals, and consumers are voluntary. As a result, many reports do not contain enough details about the event to evaluate the occurrence of adverse events appropriately. Thereby, healthcare professionals, hospitals, and consumers should be included as the responsible person to report ADR on medicinal products.

To effectively detect adverse events on medicinal products and ensure the safety of medicinal products placed on the market, the EU, the U.S., and Singapore establish a pharmacovigilance system for medicinal products and require the licensees, healthcare professionals, hospitals, patients and others to monitor, record, and submit the report of suspected adverse reactions regarding medicinal products to the competent authorities as soon as possible. In the case of danger, authority shall take regulatory actions such as changing label, issuing warnings, withdrawal or requesting the licensee to recall their product from the market.[21] Therefore, by taking the EU, the U.S., and Singapore as a model law, Thai Drug Act should be amended by adding the provision relevant to the pharmacovigilance system.

Therefore, the author recommends that Thai Drug Act should be amended by adding CHAPTER 13/1 Pharmacovigilance which should contain main issues as follows

[21] U.S. Food and Drug Administration, 'Postmarketing Safety Surveillance and Oversight: MedWatch, FAERS, and the Sentinel System' (*FDA*, 3 August 2018) <https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-priorities-2016-initiatives-and-innovation#post> accessed 10 July 2019.

The pharmacovigilance system shall be operated for the fulfillment of pharmacovigilance tasks and used to collect information on the risks of medicinal products as regards public health. That information shall refer to adverse reactions arising from the use of the medicinal product within the terms of the marketing authorization as well as from use outside the terms of the marketing authorization.

To strengthen the pharmacovigilance regarding medicinal products, The Medicinal Products Vigilance Center (MPVC), as a pharmacovigilance center, should be established with the purpose to collect adverse reactions and related problems on medicinal products, detect signals, assess adverse reactions, and report safety information to the public and related institutes in order to identify the product safety problem, manage the risk, and communicate the ADR reports with the local and international level.

The pharmacovigilance committee is responsible for assessing all aspects of risk management of medicinal products for human use, including the detection, assessment, minimization, and communication of the risk of adverse reactions. The pharmacovigilance committee consists of representatives from the Thai FDA, the independent experts in medical or pharmacological or pharmaco-epidemiological fields, and representatives from the public sector.

Licensees, healthcare professionals, hospitals, and consumers shall be the responsible person to monitor, record, and report all suspected adverse reactions on medicinal products in Thailand or third countries to the competent authorities and the Medicinal Products Vigilance Center (MPVC) as soon as possible and within 15 days from becoming aware of these reactions. These reports will send to Thai Vigibase, developed by the MPVC administered by Thai FDA, which is a national database to collects reports from medicinal product surveillance systems with the purpose to assist safety inspection of the safe and effective use of medicinal products in Thailand.

In the case of danger, the licensee shall voluntarily recall defective medicinal products or ordered by competent authorities to remove a

defective product from the market, and the Thai Food and Drug Administration shall withdraw such products from the market.

The Medicinal Products Vigilance Center (MPVC) shall communicate safety information through the bulletin, annual reports, safety alerts, and Thai FDA website. Moreover, the Medicinal Products Vigilance Center (MPVC) also sharing adverse event reports to the World Health Organization (WHO) International Drug Monitoring Programme for the international surveillance of adverse drug events and ASEAN Post Marketing Alert System (PMAS).

4. Conclusion

Thailand prescribes Drug Act of B.E.2510 (1967) (as amended in 2019) as the specific product safety law directly related to medicinal products. However, in practice, the existing safety measures for medicinal products are insufficient to protect the consumer from unsafe products and have some flaws to detect adverse events. The consequences of the ineffective of safety measures for medicinal products in Thailand can be summarized as four legal problems: 1) a long period of validity of drug registration and an absence of the review of drug formula; 2) an absence of re-evaluation of medicinal products before distribution; 3) an absence of monitoring measures by the licensee, and 4) the ineffectiveness of safety alert measure on dangerous medicinal products.

Therefore, this article has studied on the safety measures for medicinal products from three countries, namely the European Union, the United States, and Singapore in comparison which has been aware of unsafe products for many years, so these countries not only have product liability law, but also have product safety law to protect consumers and ensure that the products are safe. Thus, these three countries are good models for further development and implementation of safety measures for medicinal products in Thailand.

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Kod Krasuang Chabub Tee 20 (Por Sor 2525) Ork Tarm Kwam Nai Pra Ratchabunyat Ya Por Sor 2510 [Ministerial Regulation No. 20 B.E. 2525 (1982) Issued under the Provisions of Drug Act B.E.2510 (1967)] (กฎกระทรวง ฉบับที่ 20 (พ.ศ. 2525) ออกตามความในพระราชบัญญัติยา พ.ศ. 2510)

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COMPULSORY LICENSING FOR ACCESS TO AFFORDABLE ESSENTIAL MEDICINE (HEPATITIS C): AN INDONESIAN PERSPECTIVE*

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Abstract

Hepatitis C is one of viral diseases that requires special medication. As a viral disease, it means that it requires essential medicine for the treatment. In intellectual property, this becomes one of the issues because of the pricing of essential medicine. The inventor(s) finding this drug are entitled to an exclusive right to their invention, i.e. patent. In order to guarantee access to the medicine, it requires the regulations that regulate on how to make the patented medicine become accessible especially for Indonesia as a developing country. The TRIPs Agreement and Indonesian Law regulate this matter of compulsory licensing. Compulsory licensing is the way to make the patented medicine accessible for patients. However, even though Indonesia has implemented it, there remains problems for poor patients, and the regulations concerning compulsory licensing are still lacking in Indonesia. On the other hand, the determination of royalty for the inventor(s) must be proportional.

Keywords: Hepatitis C, Compulsory Licensing, Pricing, Regulation, Royalty

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1. Introduction

With the rising number of years, the more rapid progress of science and technology. It brings a great influence on human life, especially in the pharmaceutical and public health sectors. Also along with the increase of the population from year to year in the world as well as in Indonesia, there is greater potential for disease that can be suffered by society. With the various types of diseases, there are also many kinds of medicines needed. Thus, the human with their creativity invents various types of drugs or medicines. The recognition of findings and creations by an individual has given rise to Intellectual Property Rights.[1]

According to Black's Law Dictionary Intellectual Property (IP) is (a) category of intangible rights protecting commercially valuable products of the human intellect. It comprises primarily trademark, copyright, and patent rights, as well as trade-secret rights, publicity rights, moral rights, and rights against unfair competition. According to the World Intellectual Property Organization, IP refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names, and images used in commerce. It is divided into two categories:

1. Industrial Property includes patents for inventions, trademarks, industrial designs, and geographical indications.

2. Copyright covers literary works (such as novels, poems, and plays), films, music, artistic works (e.g., drawings, paintings, photographs, and sculptures) and architectural design. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and broadcasters in their radio and television programs.[2]

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[1] Sartika Nanda Lestari, 'Implementasi Compulsory Licensing Terhadap Obat-Obatan dalam Bidang Farmasi di Indonesia' (Studi Berdasarkan Doha Declaration on the TRIPS Agreement and Public Health) (Thesis, Master Program on Jurisprudence Diponegoro University, Semarang 2012) 17.

[2] World Intellectual Property Organization, 'What is Intellectual Property' <www.wipo.int,> accessed 4 September 2019.

Indonesia, as a developing country has many types of diseases, even fatal diseases. In 2013 the prevalence of hepatitis C in Indonesia increased among children at the age of 15 years or below. One type of hepatitis that infects the population of Indonesia is Hepatitis C (2.5%).[3] Hepatitis C is a liver disease caused by the hepatitis C virus (HCV): the virus could resulted in both acute and chronic hepatitis, ranging in severity from a mild illness lasting a few weeks to a serious, lifelong one.[4] Hepatitis C virus infection is a global health problem and is the main cause of chronic liver disease worldwide.[5] Globally, approximately 71 million people have chronic hepatitis C virus infection. WHO estimated that in 2016, approximately 399,000 people died from hepatitis C, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer).[6] In Indonesia, viral hepatitis is a significant public health problem. Currently, around 2.5 million are infected with HCV.[7] The national prevalence of HCV has remained stable and predicted to remain at its current level without focused intervention.[8] Since hepatitis C remains one of the health problems in developing country especially Indonesia, Indonesia needs to facilitate access to those medicines. However, the problem is their high prices that cause them inaccessible.

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[3] Kementerian dan Kesehatan Republik Indonesia, 'Situasi Penyakit Hepatitis B di Indonesia Tahun 2017' *Infodatin (Pusat Data dan Informasi Kementerian Kesehatan RI,* 2017) 2.

[4] World Health Organization, 'Hepatitis C' <www.who.int> accessed 5 September 2019.

[5] Muhammad Umar, *et al,* 'Diagnosis, Management, and Prevention of Hepatitis C in Pakistan 2017' (2016) 28(4) Journal of Ayub Medical College Abbottabad-Pakistan 839.

[6] World Health Organization (n 4).

[7] Jonathan Scrutton, Jack Wallace, and Suzanne Wait, 'Situation Analysis of Viral Hepatitis in Indonesia: A Policy Report' (*Coalition to Eradicate Viral Hepatitis in Asia Pasific,* July 2018) 12.

[8] ibid, cited from Sibley A, Han KH, Abourached A, et al. 2015, 'The present and future disease burden of hepatitis C virus infections with today's treatment paradigm' Vol 3 J Viral Hepat 22 Suppl 4, 21-41.

The access to medicines strongly relies on pricing and financing mechanisms that can be differently applied to each country. In developing countries, in the absence of broad health coverage systems, a large part of expenditure comes from patients' own pocket, provided, of course, that their level of income allows them to afford it. This does not happen, however, in many cases where medicine prices are inaccessible to various segments of the population. As medicines are financed by a third-party payer, high prices are the biggest source of pressure on the budget.[9] This pricing issue is due to the patent right of a patent holder. The notion of Intellectual Property Rights is based on the principle that the person who made an intellectual contribution must have an exclusive right to enjoy the fruits of his labor.[10] As a result, the monopoly practice might happen because of the principle of this exclusive right that the patent holder could use the right within a certain period of time. This exclusive right gives a patent holder the right to monopolize through pricing and medication restriction. The practice of monopoly rights makes the developing countries such as Indonesia unable to access essential medicines. Indonesia is one of the countries that urges the application of certain policies on the use of patents on essential drugs (self-producing patented medicines) to reduce the cost of essential medicines for which the patents have been registered.[11] Self-producing patented medicines means to produce generic

[9] Carlos M. Correa and German Velasquez, 'Access to Medicines: Experiences with Compulsory Licenses and Government Use – The Case of Hepatitis C' (2019) South Centre Research Paper 85, 1.

[10] Muhammad Zaheer Abbas and Shamreeza Riaz, 'Evolution of the Concept of Compulsory Licensing: A Critical Analysis of Key Developments before and after TRIPS' (2013) 4(2) Journal Savap Academic Research International, 482.

[11] Sartika Nanda Lestari (n 1) 28.

version of certain drugs that are still protected by patent, either through compulsory licensing or government use.[12]

This situation could lead to non-accessible drugs for poor patients. According to Article 28H paragraph (1) of the 1945 Constitution, which stipulated that *"Each person has a right to a life of well-being in body and mind, to a place to dwell, to enjoy a good and healthy environment, and to receive medical care."* Based on this stipulation, it is clear that everyone has the right to a life of well-being in body and the right to receive medical care. Related to the health policy in Indonesia, as one of the examples of developing countries, health is one of the eleven priorities in the national development program. It is stipulated in the Regulation of the President of the Republic of Indonesia Number 5 of 2010 on the National Medium-Term Development Plant (RPJMN) 2010-2015. Furthermore, the right to health is also recognized as human right based on the Act Number 36 Year 2009 regarding Health. Article 5(1) of the Act number 36 Year 2009 states: "Every people shall have equal right in obtaining access to health resources". It has been stipulated also in Article 16 of the Act Number 36 Year 2009 that the Government shall be responsible for the availability of fair and proportional distributed resources of health for all people in order to achieve maximum health degree.[13] Thus, Indonesia must make drugs for viral disease affordable, especially where the country does not yet have local or insufficient manufacturing in the pharmaceutical sector for making these drugs. Therefore, the DOHA Declaration on the TRIPS Agreement and Public Health, which was enacted in 2001, becomes relevant.

The WTO Director General's speech conveyed that each WTO member country has the right to regulate flexibility over drug patents. This

[12] Tomi Suryo Utomo, 'Implikasi Pasal-Pasal Pelindung (The TRIPS Safeguards) Dalam UU Paten Indonesia: Kritik, Evaluasi, dan Saran Dari Perspektif Akses Terhadap Obat Yang Murah dan Terjangkau' (2007) 14(2) Jurnal Hukum, 272.

[13] Sri Wartini, 'The Legal Implication of Compulsory License Pharmaceutical Products in the TRIPs Agreement to the Protection of the Right to Health in Developing Countries' (2018) 18(1) Jurnal Dinamika Hukum, 5.

flexibility is called compulsory licensing, which is expected to be able to answer problems faced by countries that could not afford to buy patented drugs or do not have capabilities and are less able to produce drugs on a local scale.[14] According to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, where it is stated that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement" it could be said that compulsory licensing is a form of freedom/rights given to developing countries for making, accessing or selling drugs "second class" for drugs that have been patented with the aim of public health.[15] Under Article 31 on Other Use Without Authorization of The Right Holder of the TRIPs Agreement, Section 5 on Patent, there are four requirements for granting a compulsory license which are, as follows:

a. Emergency and extreme urgency;
b. Anti-competitive practice;
c. Public non-commercial use;
d. Dependent patents.

The regulation makes the situation for Indonesia as one of the developing countries more flexible in accessing the essential drugs for hepatitis C disease and could increase people's welfare. Thus, Indonesia implements this by passing a regulation which is Government Regulation Number 39 of 2018 on Procedure for Granting a Compulsory License. However, this is quite challenging for the Indonesian Government as well. This research would discuss the issue that high pricing remains a problem despite the Government's effort to implement the compulsory license policy, mainly because of the lack of regulations concerning the compulsory license in Indonesia; and the royalty determination issue.

[14] Samariadi, 'Pelaksanaan Compulsory Licensing Paten Obat-Obatan Bidang Farmasi di Indonesia Dikaitkan Dengan *DOHA Declaration on the TRIPS Agreement and Public Health'* (2016) 1(2) *De Lega Lata*, 451.
[15] ibid.

2. Pricing Issue of HCV Medicine in Indonesia

A compulsory license can be issued by a government to allow a local company to manufacture the patented product or to import it under certain conditions.[16] Article 31(f) of the TRIPS Agreement stated that "*any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.*" However, a mechanism put in place in 2003 allows WTO members to waive this condition to grant special compulsory licenses for the manufacture and export of generic medicines to countries that do not have local manufacturing capacities in order to supply the needed medicines to their patients.[17] However, unlike Malaysia which imported generic versions of the drugs from India, Indonesia used the compulsory license to appoint local manufacturers to produce 7 medicines for treating Hepatitis B and HIV/AIDS based on Decree of the President Republic of Indonesia No. 76 of 2012.[18] This also happens in the case of hepatitis C medicine.

Historically, Indonesia's pharmaceutical drug utilization has been the lowest in the region compared to neighboring markets; however, with its trend of significant and sustained population growth, the country is seeing increasing demand for access to safe, effective medications and healthcare services. In particular, Indonesia's changing epidemiology of chronic illnesses such as diabetes, obesity, cardiovascular diseases, and other similar conditions has revealed a rise in related incidence as well as unprecedented healthcare needs.[19] This includes hepatitis C disease. In this situation, Indonesia has improved in several ways. The recent investment in manufacturing facilities comes amid an expected rise in demand for

[16] World Health Organization, 'Global Report on Access to Hepatitis C Treatment' (*WHO*) <www.who.int,> accessed 28 October 2019, 26.

[17] ibid; *see* http://www.who.int/phi/promoting_access_medical_innovation/en.

[18] Sri Wartini (n 13) 7.

[19] Global Business Guide Indonesia, 'Indonesia's Pharmaceutical Industry is in Rude Health' (*Global Business Guide Indonesia*) <www.gbgindonesia.com> accessed 28 October 2019.

domestically made generic drugs, driven by government efforts to expand national health insurance offerings.[20] In 2014 officials launched the Jaminan Kesehatan Nasional scheme, which aims to provide universal health coverage to Indonesian citizens by 2019. Given the significant expansion of services required to meet this objective, the use of unbranded or generic medicines has been encouraged in order to reduce costs.[21]

The existence of compulsory licensing on hepatitis C medicine is a tool for accessibility. Now, there is DAA (Direct Acting-Antiviral) medicine which is generic medicine of hepatitis C with *sofosbuvir*[22] type. The distribution permit of this medicine has been approved by BPOM (National Agency of Drug and Food Control). The producers of this generic medicine are PT. Soho Indonesia and PT. Kimia Farma. The *sofosbuvir* tablet approved by the BPOM is a product with the trade name Sovaldi (registrant PT. Soho Indonesia, approved June 30, 2016). Also PT. Kimia Farma as the registrant for the *sofosbuvir* with the trade name Myhep (approved July 1, 2016).[23]

Pricing issues were the most important problem for compulsory licensing in Indonesia. Despite the fact that Indonesia has applied compulsory license for DAA or generic version of hepatitis C medicine, the access to DAA remains limited because pharmaceutical companies set prices that are not affordable. *Sofosbuvir* price in Indonesia is 10 times more expensive than that in India. This is proven by data in September 2017 when *sofosbuvir's* price in India was only $14 or around 200,000 ruphias,

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[20] Oxford Business Group, 'Indonesia Bolsters Domestic Pharmaceuticals Production Capacity' (*Oxford Business Group*) <www.oxfordbusinessgroup.com> accessed 9 November 2019.

[21] ibid.

[22] According to Indonesia National Agency of Drug and Food Control, Sofosbuvir is a nucleotide prodrug that will undergo intracellular metabolism into an active form of uridine triphosphate analogue, which is a non-structural (NS) 5B Ribonucleic Acid (RNA) polymerase inhibitor of Hepatitis C virus (HCV).

[23] Badan POM, 'Badan POM Menyetujui Izin Edar Sofosbuvir, Obat Hepatitis C' <www.pom.go.id,> accessed 20 November 2019.

while in Indonesia the price was around 2,200,000 ruphias.[24] This could lead to the crisis of scarcity of hepatitis C medicine due to the monopoly practice conducted by pharmaceutical companies, as Indonesia only has two pharmaceutical companies in the market.

To solve the problem mentioned above, *first,* Indonesia must encourage the research and development (R&D) investments that can produce new drugs especially ones on hepatitis C disease by enlarging the incentive scheme. Based on data in 2019, in Indonesia 95% of drug raw materials remains dependent on imports.[25] As such, with R&D investments, Indonesia would no longer rely on compulsory licensing of hepatitis C medicine. *Second,* the R&D to find a new medicine must be associated with encouraging local production which is a long-term sustainable development. Lower prices can also be achieved by supporting local production of drugs through voluntary licensing and technology transfer. The authorization of technology through technology transfer is much cheaper than buying new technology.[26] Technology transfer is the implementation of developing countries' rights to obtain technology from developed countries. This could be seen in Declaration on the Progressive Development of Principles of Public International Law Relating to A New International Economic Order.[27] In its process, there are parties involved, which are, the owner of technology as the party providing the technology, the State that owns the technology,

[24] Whisnu Bagus Prasetyo, 'Obat Hepatitis C di Indonesia Lebih Mahal 10 Kali Lipat Dibanding India' (*Berita Satu*, 29 July 2018) <https://www.beritasatu.com/nasional/503222/obat-hepatitis-c-di-indonesia-lebih-mahal-10-kali-lipat-dibanding-india> accessed 21 November 2019.

[25] Dewi Rachmat Kusuma, 'Jokowi: 95 Persen Bahan Baku Obat Masih Tergantung Impor' (*Kumparan Bisnis*, 21 November 2019) <https://kumparan.com/kumparanbisnis/jokowi-95-persen-bahan-baku-obat-masih-tergantung-impor-1sIR5Ov5VZt> accessed 21 November 2019.

[26] Slamet Yuswanto, 'Upaya Mewujudkan Alih Teknologi Melalui Waralaba' (2019) 4(1) UBELAJ, 73.

[27] ibid.

the technology recipient as the party as well as the State receiving the technology.[28] This is a long-term, sustainable strategy that has the added benefits of stimulating the economic development and enhancing autonomy of developing countries.[29] Industrialized countries should extend technology transfer as well to countries that already have some manufacturing capacity, as these will be the best candidates to start manufacturing drugs that are out of reach mainly because of price.[30] These solutions can also benefit developing countries that could become regional suppliers and could make the price of hepatitis C medicine more affordable for patients.

3. Implementation of Indonesian Compulsory Licensing: Lack of Regulations

One of the legal implications of compulsory licensing is the accessibility and affordability of the essential medicine which are deserved by patients in developing countries, such as *Antiviral* and *Antiretroviral,* since the developing countries can use the justification based on the reason of protecting public health and also the developing countries have a freedom to issue the law to determine what emergency situation to justify the implementation of compulsory license. Thus, the compulsory license enables state to protect the right to health.[31]

The procedure to grant a compulsory license is, however, governed by the respective national (patent) law, which has to define the specific grounds for which a compulsory license can be granted as well as the procedure to be followed.[32] Hence, the Indonesian Government has already

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[28] ibid, 74.

[29] Ellen 't Hoen and Suerie Moon, 'Equity Pricing of Essential Medicines in Developing Countries'<https://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/15thoen_e.pdf> accessed 23 November 2019.

[30] ibid.

[31] Sri Wartini (n 18) 6.

[32] World Health Organization (n 6).

amended the Patent Act by following the TRIPs Agreement. The reason for exercising compulsory license in Indonesia is based on Article 109 of the Indonesian Patent Act. With the existence of Patent Law specifically concerning compulsory licensing, it is necessary to have further provisions in the form of Government Regulation. However, the lack of regulation of compulsory licensing in Indonesia has become one of the problems in the patent law. Government Regulation concerning compulsory licensing still does not exist. There is only Ministerial Regulation Number 39 of 2018 concerning the Procedures for Granting of Compulsory Licensing.

The regulation came as a surprise for many companies, especially as there was no prior consultation with the private sector in its drafting process. Initial reading shows the regulation needs further clarity in terms of scope, urgency and technical guidelines as some articles contain very general and/or vague provisions related to compulsory licensing implementation.[33] This could be seen in Article 22 of Ministerial Regulation Number 39 of 2018. Article 22 specifically governs the use of compulsory licensing for pharmaceutical products, which states that the Minister of Law and Human Rights may grant compulsory licensing to produce, import and export pharmaceutical products with patents in Indonesia for the purpose of "curing human disease". From that statement, there are no further details in the article on how it will be implemented.[34]

The release of the regulation also potentially contradicts Ministerial Regulation No. 15 of 2018 on the Postponement of Local Manufacturing Requirements, which allows patent holders to delay the implementation of local manufacturing for five years, and can be extended. The release of the compulsory licensing regulation opens up a greater risk for patent holders applying for a postponement that their product will be requested for compulsory licensing.[35] Therefore, in this case, Indonesia needs to enact the

[33] Gilang Ardana, 'Government Releases Compulsory Licensing Regulation' <www.amcham.or.id.> accessed 24 November 2019.

[34] ibid.

[35] ibid.

government regulation specifically concerning compulsory licensing as the implementing regulation of patent law, not only the ministerial regulation. Despite the fact that there are Government Regulation Number 27 of 2004 on Procedures for Patent Exploitation by Government Use and Presidential Decree No. 83 of 2004 on Patent Exploitation by the Government on Anti Retrieval Medicine that the Government has been using those rules in implementing compulsory licensing, it is inadequate and is not well targeted in regulating the compulsory licensing because in essence, compulsory licensing and Patent Exploitation by Government Use are different. Also, specifically, Indonesian Intellectual Property Rights Law has mandated in its Article to regulate further provisions regarding license agreement with government regulation, however, until now the government regulation has not been ratified.[36] This leads to the consequence that Indonesia is still lacking in the regulation of compulsory licensing, which is the government regulation as the implementing regulation to the correspond laws of patent for the parties in the case of compulsory license.

The issue of lacking in regulation for the payment of royalty to the inventor(s) under compulsory licensing is also a problem. Because there is only a regulation concerning royalty on patent exploitation by government use. The royalty regulation concerning compulsory licensing is still missing. From this situation, in order to provide good regulations regarding compulsory licensing, for the sake of prosperous society especially in the health sector which is for hepatitis C patients in Indonesia, the enactment of government regulation concerning compulsory licensing must be done as soon as possible. This also intended to provide legal certainty to the parties in patent activities regarding compulsory licensing, specifically in pharmaceutical sector.

[36] Sulasno, 'Lisensi Hak Kekayaan Intelektual (HKI) Dalam Perspektif Hukum Perjanjian di Indonesia' (2012) 3(2) *Adil Jurnal Hukum,* 357.

4. Determination of Royalty: The Right of Inventor(s) and the Patent Holder(s)

Article 31 letter (h) of TRIPs Agreement stated that "*the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization".* In Indonesian Patent Law, Article 1 number 14 stated that royalty is compensation given for the use of patent rights, which is further explained in Article 1 number 15 about the meaning of compensation itself. Thus, we can conclude that patent royalty is fee granted by the patent applicant to the inventor(s) for the results of their invasion in certain fields of technology, specifically in this case is medicine. Royalty concerning the granting of compulsory license in pharmaceutical products is regulated by Article 92 and Article 93 of Law No. 13 of 2016 on Patent. Further provisions regarding the calculation of royalty on Patent in Indonesia is regulated by Ministerial Regulation No. 72/PMK.02/2015 on Compensation from Non-Tax State Royalty Income to Inventor(s). However, this Ministerial Regulation only applies to royalty payment for the patent by government use. If the patent is not carried out by the government, the procedure for royalty payment shall be determined by an agreement agreed between the inventor and the patent holder. The issue of royalty is also regulated under Government Regulation No. 27 of 2004 on Procedures for Patent Exploitation by Government Use Article 10. However, as it already explained in the previous sub-chapter, this Government Regulation is inadequate and not well targeted in regulating compulsory licensing.

The determination of royalty rates on compulsory licensing is also one of the issues in this case. The question is whether the rate could be classified as an adequate remuneration for the inventor(s) or not. A more important reflection is what adequate remuneration should amount to. Due to the obvious reason that most developing countries lack available funds, which makes them unable to pay even modest royalties without financial assistance and so leaving the flexibility unreachable. The consequence will be the same if royalty rates are set too high. Conversely, low royalty rates

may well lead to an excessive use of compulsory licenses, which in turn, might be perceived by pharmaceutical companies as excluding monopoly profits and putting investments at stake. Hence, the risk in this situation is that compulsory licensing could undermine incentives for R&D investments and slow down the development of new drugs.[37] Thus, the role of the government in making regulation regarding royalties payment of compulsory license, should take into account on how to provide proportional royalties to inventor(s), so that no party feels disadvantaged.

5. Conclusion

Since hepatitis C is one of chronic diseases that could resulted in death and supposedly requires special medication, it causes problems. The first problem is about the pricing of the medicine itself. Indonesia as one of developing countries, usually lacking fund, has to implement compulsory licensing for patent medicine (hepatitis C) in order to improve its citizens' right to health according to the TRIPs Agreement and Indonesian Patent Law. However, it turns out that compulsory licensing is still not the right solution because of the inaccessibility problem, especially for poor patients. Despite the existence of compulsory license that could make the medicine affordable, the costs are still 10 times more expensive than those in India. To solve the problems, Indonesia must make R&D investments, at once, with the incentive scheme that continues to be improved in order to find new drugs for hepatitis C. Transfer of technology is also needed to support this.

The implementation of compulsory license in Indonesia has been running for a long time. Yet, the regulation of compulsory license is still lacking. Indonesia in implementing compulsory licensing is still bound to use the government regulation No. 27 of 2004 on Procedures for Patent

[37] Anna Niesporek, 'Compulsory Licensing of Pharmaceutical Products & Access to Essential Medicines in Developing Countries' (Thesis**,** Linköping University, Sweden 2005) 30.

Exploitation by Government Use where the substance patent exploitation by government use and compulsory license are different. Thus, the government should enact new government regulations focusing specifically on the compulsory license, so that the parties get legal certainty.

The problem of determination of royalty is also important for making regulation that give proportional royalties to the parties, so that no party feels disadvantaged. Thus, the government role is very important in determining royalties for compulsory license scheme.

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