



Legal Protection against Patent and Intellectual Property Rights Violations Amidst COVID-19

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Abstract

The concept of legal principles for intellectual property (IP) protection is related to the adequate marketing of drug patents to protect patent rights. The objective of this research is to understand and analyze the factors affecting the market concerning international law, treaties, acts, and declarations, leading to encouraging creativity, production, increased investment, especially amidst the COVID-19 pandemic. The qualitative methodology provided for an in-depth understanding and analysis of primary and secondary research data gathered from key informant interviews and published literature. The collected data were analyzed with Strength, Weakness, Opportunity, and Threats (SWOT), a Delphi panel, and Correct, Adapt, Maintain, and Explore (CAME) analysis. The results found legal problems concerning the lack of rules to protect the rights and freedoms damaged by the monopoly on drug patents, complexities in the process of importing medicinal compounds, and how to access information with limited accessibility during COVID-19. Therefore, it is advisable to amend the law to curtail monopolies and to enact a law that prescribes rules for importing medicinal compounds to produce generic drugs in the country, including identifying the status of the patent holders. The research further paves the way for utilizing micro level research to be conducted in the development of intellectual property rights.

Keywords:

Patent Rights; Drug Market; Liability to Patent Right Holders; Intellectual Property Rights; World Trade Organization (WTO); Free Trade Agreements (FTAs); World Intellectual Property Organisation (WIPO).

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1- Introduction

Intellectual property rights have been attracting attention in many countries due to the complexities of national and global economies [1]. In particular, the United States has pushed the General Agreement on Tariffs and Trade (GATT), which sets out minimum standards for intellectual property protection for GATT member states to comply with; however, the United States uses this as a tool to achieve effectiveness [2]. The United States has used trade countermeasures against trading partners who have unfair trade policies against the United States or do not provide adequate protection of intellectual property rights. Countermeasures are used, such as import restrictions, delisting of trade privileges, etc. The World Trade Organization (WTO) was established as a result of the fact that foreign countries had approved several international agreements, including the Marrakesh Agreement. Consequently, the World Trade Organization was established, which resulted in the ratification of the final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiation. This established the foundation of intellectual property rules under the agreement on Trade-Related Intellectual Property Rights (TRIPS) [3, 4]. Thailand, as a member state of the World Trade Organization, is obligated to comply with the rules that require member states to provide a comprehensive IP law enforcement process and ensure efficient and fair jurisprudence for the involved parties. Although the provisions in

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TRIPs do not require WTO member states to establish special courts to protect intellectual property rights, however, the Thai government deems that there is an intellectual property and international trade court in the country. The existence of this legal framework tries to ensure the law enforcement process is efficient and fair to all parties (Table 1).

Table 1. International agreements and treaties related to the IPL

Intellectual property	Protection/ Rights	International Trade Agreements
Industrial	Patents, Models and Designs	Paris Convention, Patent Cooperation Treaty, Budapest Treaty, Strasbourg Agreement, Hague Agreement, Locarno Agreement, TRIPS
	Trademark	Madrid Agreement, Nice Agreement, Vienna Agreement
	Geographical Rights	Lisbon Agreement, TRIPS
Literature and Art	Copyright	Berne Convention, Rome Convention, Geneva Convention, Brussels Convention, WIPO, Copyright Treaty, WIPO Performances and Phonograms Treaty, Universal Copyright Convention, Marrakesh Agreement TRIPS
<i>Sui Generis</i>	Database, Integrated Circuits and Plant Breeding	Washington Treaty, TRIPS, EC Directive 96/9/EC UPOV TRIPS
Trade Secrets	Unfair Competition	TRIPS

In Thailand, intellectual property rights in the field of medicines, which are part of the health system, tend to account for higher costs [7–9]. There has been a rise of about 30 percent in health expenditures from 1995 to 1999 and then to 40 percent since 2003 [10]. Data from the National Drug Expenditure List reveals that the value of domestic drug consumption at consumer prices in 2010 was 144,570 million baht, which was divided into consumption through hospitals, drug stores, nursing homes, and other medical centers. The Intercontinental Marketing Service (IMS) found that the overall market share data reflected that the sharp increase in drug expenditures was caused by high-density drug use [11]. The single seller (single source), which was absent in the domestic market and must be imported from abroad. This trend has continued to grow over the past three decades. Hospitals are the main distribution channel in Thailand. Medicines distributed through public and private hospitals had an approximate value of 70 billion baht in 2008, an increase of 16% from 2007. The price of the drug sold in Thailand is higher than it should be compared to the international reference price in recent years. The median price of a prototype drug sold to patients by public hospitals in Thailand is higher than the international reference price with additional charges; however, if bought from a drugstore, it is found that the price is as high as 6.11 times higher. The prices of the drugs are coordinated and managed by the Drug and Medical Supplies Information Center (DMSIC), which works in collaboration with the National Average Drug Acquisition Cost (NADAC), National List of Essential Medicines (NLEM), and the data is maintained by the National Statistical Office (NSO) in Thailand. However, the affordability and protection of both drug patent holders and consumers are vulnerable in Thailand due to the challenge of maintaining the rights of all the parties involved [12].

However, it is worth considering the significant impact on Thailand from the EU-Thailand Free Trade Agreement on patents in terms of laws, regulations, and policies, as well as the tendency for EU free trade agreements with other countries [13]. The significant findings of the previous literature consisted of standards, rules, and regulations. The laws in Thailand are the result of the adoption of European Union guidelines on issuing patents in Thailand. There are seven laws to protect intellectual property that are under the responsibility of the Department of Intellectual Property, namely: Patent Act BE 2552 (2009), which was amended by the Patent Act (No. 2) B.E. 2535 and the Patent Act. (No. 3), B.E. 1999; Trademark Act, B.E. 1991, that was amended by the Trademark Act (No. 2), B.E. 2543 (2001); Copyright Act, B.E. 1994; Integrated Circuit Layout Protection Act, B.E. 2000; Trade Secret Act B.E. 2545 (2003); Geographical Indication Protection Act B.E. 2546 (2004); and CD Products Act B.E. 2548 (2006) [14-17].

In addition, intellectual property disputes are a complex issue for ordinary judges to have expertise in this particular law, especially at present with higher technological developments [18]. This has led to more complex infringements on intellectual property rights. The importance of protecting intellectual property and international trade is seen in the declining economic growth of Thailand. Therefore, the Intellectual Property and International Trade Court was established as a legal framework and system to ensure a fair and just system. To serve in the trial and adjudication of intellectual property and international trade cases, a specialized court was convened. There is a special method of trial that is different from the ordinary court, and judges acting in adjudication must be those who have specific knowledge and abilities related to their experiences in IPL.

Thailand has a drug data protection agreement with the European Union [19], which affects the period of market monopoly which may enhance Thailand's vulnerabilities because, at present, there is no prototype drug factory in Thailand. The prototype drug used to treat patients or sold in Thailand must be imported from abroad. The majority of Thai generic medicine imports come from India and China, which is more than ninety percent of the total importation of medicinal compounds to produce generic drugs in the country [20]. In the past, Thailand has not imported prototype drugs from India and China [21]. This is because the original drug was given very high importance due to the brand credibility of the drug-producing country. By the proportion of the quantity and value of the prototype drug to the generic

drug in the Thai public health system, it was found that the value of the prototype drug was approximately three-fourths of the total use of the drug in the country, and the quantity of the original drug was about 50 percent of the total drug use in the country. The previous studies are limited to the Free Trade Negotiation Articles between the EU and key countries about the Patent Extension to compensate for delays in drug registration and protection of drug test data (Protection of Undisclosed Information or Data Exclusivity: DE), whereas a focused study in the Thai context is still unexplored. There have been a limited number of previous studies focused on the intellectual property rights and protection of patent rights holders in Thailand. The contextual understanding of the Thai legal system is ineffective in terms of curbing the monopoly of the drug market.

1-1- Study Objectives

The objective of this study is to understand and analyze the patent and marketing relationship in terms of intellectual property rights.

- To study the history, concepts, and theories related to patent protection in intellectual property in case of liability to rights holders.
- To study the legal measures on protection of Intellectual Property patents in cases of liability to the rightful holder among international and Thai law.
- To analyze legal problems related to the protection of Intellectual Property patents in cases of liability to the rightful holder.
- To propose guidelines for improving Thai law on the protection of Intellectual Property patents in cases of liability to the rightful holder.

2- Literature Review

At present, those who wish to apply for patent registration can apply for a patent certificate in the European Union (EU). Patents are granted directly by the competent authority of the country or the European Patent Office under applicable EU regulations [22]. Many patent authorities in the European Union have mechanisms for extending the patent protection period for pharmaceutical products under certain conditions. Companies can apply for additional certificates of protection (Supplementary Protection Certificates- SPCs) for pharmaceutical products that are already approved by European Economic Community (EEC) regulations when the term of market exclusivity obtained from a patent is less than 15 years from the date of the first patent application. For the legal systems of the member states and countries in the European Economic Area (EEA), additional protection certificates are provided. SPCs that extend patent protection for drugs are governed under the EEC. Most of these are for a maximum of 5 years, such as in EU member states that have additional protection certificates (SPCs), such as France, Germany, and the United Kingdom. The authorized premises of a member state may determine other powers and duties responsible for applying for a patent.

The category of products covered by additional protection certificates (SPCs) is pharmaceutical products. As in Regulation (EC) No. 469/2009, it applies to any pharmaceutical product that is patent protected within the territory of a member state and is subject to a licensing procedure before being marketed in the member state [23]. In terms of principles and theories related to patent protection in intellectual property rights, in cases of liability to rights holders for damages arising from drug patents, they include 469/2009, which applies to any pharmaceutical product that is patent protected within the territory of the member state. This is subject to authorization procedures performed marketed in the member state.

The principles governing the protection include the principle of transparency (transparency), principles of effectiveness and efficiency, the rule of law, and Corporate Governance principles of independent organizations for Consumer Protection of Health Products [24, 25]. Although there is currently no internationally standardized definition of a health product, which is the same in the case of Thailand, health products are products that the FDA is responsible for and that consist of 8 types of products, including drugs, narcotics, psychotropic substances, volatile substances, medical devices, food, cosmetics, and hazardous substances from overseas health product consumer protection system reviews include China, Japan, the European Union, the United States, and Australia. Previous literature depicts that in foreign countries, there is a consumer protection agency for each health product. The organizational structure is designed to be linked to the departments. The roles and standard operating procedures (SOP) are defined to reduce work overlaps and create specializations.

Thailand is struggling to provide for the effectiveness of IP rights and patent right holders' protection; however, the current legal system and framework are inadequate to curtail the short- and long-term adverse implications of violations of the IPR [26–28]. The exemplary literature from previous studies depicts Thailand's laws as inadequate when compared with other countries [29, 30].

The scope of this research examines the relationship between copyright law and human rights law and measures that directly impact various copyright laws, which will be considered in terms of patent medicine by studying the Constitution of the Kingdom of Thailand, B.E.2017 and the Copyright Act 1994. These acts are compared with the Universal

Declaration of Human Rights, the International Covenant on Economic, Social, and Cultural Rights, the Agreement on Intellectual Property Rights, related to trade (Agreement on Trade-related Aspects of Intellectual Property Rights), and the laws of foreign countries such as the United Kingdom and the United States [31]. This has been adversely enhanced in the recent COVID-19 pandemic scenario in most parts of the world and especially in Thailand [32]. By focusing on the study of human rights principles related to copyright law, various measures under copyright law that adversely affect human rights. This is to seek legal principles and appropriate guidelines for formulating copyright law by human rights to create a balance between the interests of the copyright owner and the public interest.

3- Research Methodology

The research adopts a descriptive methodology involving exploratory desk research, which explores the research gaps and problems related to patent protection in the intellectual property of drug patents. The qualitative research methodology provided for in-depth understanding and analysis of primary and secondary research data gathered from key informant interviews and published literature. The documents obtained from primary data collection and secondary data from various sources both domestically and internationally were analyzed with Strength, Weakness, Opportunity, and Threat (SWOT), Delphi panel, and CAME analysis.

This study is a documentary research study by using a study and analyzing data from documents by studying legal principles about the protection of persons' rights in the damage caused by drug patents. The secondary data was collected from books, textbooks, research reports, articles from journals, government publications, dissertations, and information sheets from government and private organizations. Apart from these, various documents in both Thai and foreign languages, including information obtained from international networks or the internet and legal opinions related to the protection of rights and the implications of legal principles.

The research follows a research design by focusing on the descriptive nature of the data collected and analyzed by a panel of experts. The research was conducted with a focus on intellectual property rights and the legal framework to protect rights holders in Thailand. The key experts from the field of the legal framework in Thailand and the protective agencies in Thailand were approached through the random snowball method. The experts were designated with the preliminary findings, which resulted in the analytical interpretations for further analysis.

The methodology involves analysis from the SWOT-Delphi panel and then CAME analysis to provide for a holistic and comprehensive analysis of all the legal frameworks to protect the rights holders [33]. The panelists are chosen, and their expert opinion is provided for the variables to be studied. This was merged with extensive SWOT analysis based on descriptive methods. The output was then analyzed again with the CAME analysis.

The Delphi panel has been developed to gather the expert opinions of legal stakeholders for the protection of rights holders. The anonymity of the panelists provides an unbiased opinion regarding the variables under consideration [34]. It was ensured that the legal stakeholders are directly related to the implementation of the rules and regulations in Thailand. This provided a realistic panel to analyze the ground-level realities of the effectiveness of the legal framework in Thailand [35].

The panel provided for futuristic approaches towards the right holder's protection, ensuring the economic benefits to be curtailed and enhancing the legally binding protection for all the right holders. The collected opinions and expert inputs were analyzed through CAME analysis. CAME analysis comprises Correct, Adapt, Maintain and Explore (CAME) analysis. It coincides with the SWOT analysis and provides for the further development of legal strategies to ensure the protection of legal rights holders [36].

Figure 1, shows the flowchart of the research methodology through which the objectives of this study were achieved.

4- Results and Discussions

The legal measures regarding patent protection in intellectual property rights in cases of liability to rights holders for damages arising from drug patent violations in Thailand were found to be inadequate. There are various issues regarding the legality of patent protection, which are discussed below.

Currently, the economy of Thailand is expanding rapidly. The knowledge of science and technology is used in the production of experiments for drug marketing. These enhanced marketing mechanisms of experimental drug manufacturers influence the rights of patent holders. It is found that the legal framework is lacking in terms of knowledge of quality drugs and bargaining power. The warranty of drugs, pricing, safety for life, and protection of the rights of the people have always been taken advantage of, incidentally, whenever a dispute arises. The process of filing a claim for damage is costly and time-consuming. Consequently, litigation for the victim's rights falls into a disadvantage, which is unfair and affects the overall economic system of the country. It is expedient to have rules for protecting the rights of a person who has been damaged by the manufacturer's drug; however, the legal framework does not comply with the standards conducive to the exercise of the claims of the right, so those who have been damaged can be healed quickly, economically, and efficiently. At the same time, it encourages manufacturers of drugs, which results in a focus on the development of quality drugs in Thailand.

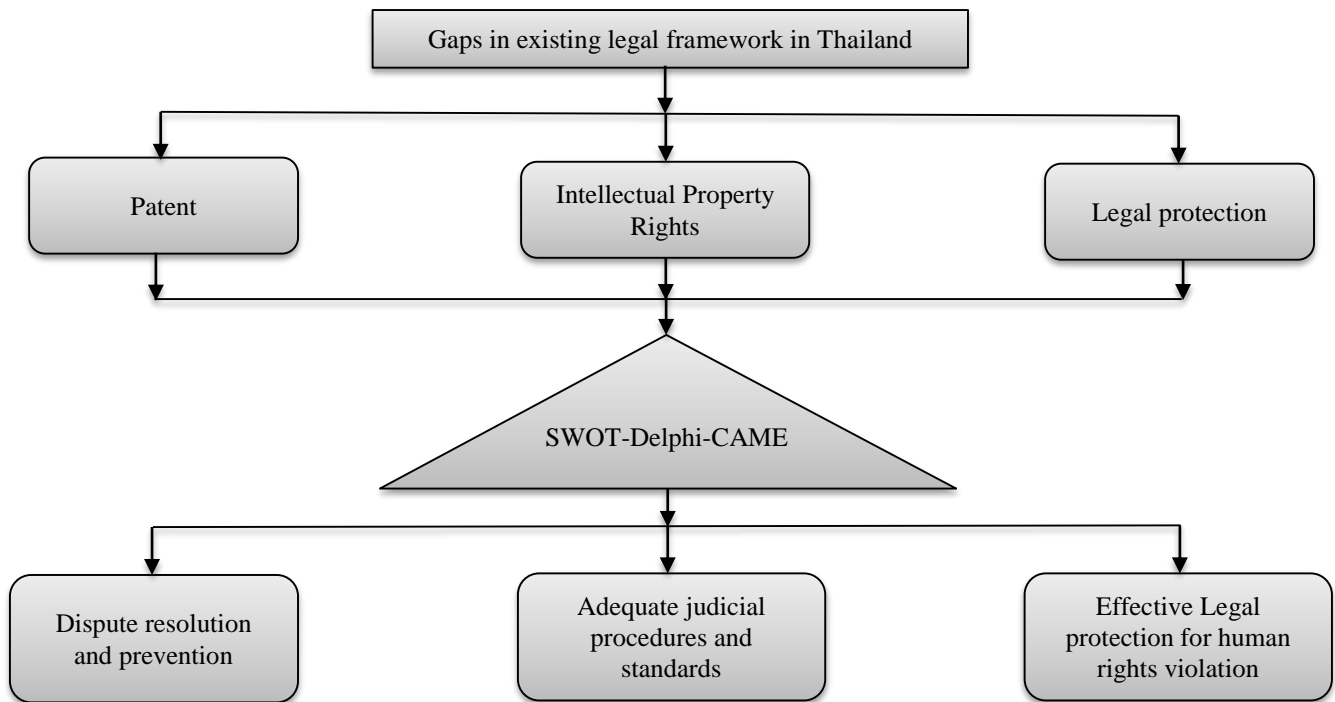


Figure 1. Conceptual framework for this research

It was found that the legal framework is inadequate to protect patent and intellectual property rights in Thailand. Considering the constitution of the Kingdom of Thailand, the 2560 B.E. Act, which certifies the protection of the rights of consumers and consumer organizations. The regulatory framework projects the will to protect the patent holders and to be united and established as an independent organization to ensure impartiality. However, the current legal scenario is not found to be just and fair and to create the power to protect the rights of consumers. The governing bodies are unable to protect the physician, and victims were unable to attain support from the state. The rules and methods of establishing the power to represent the right consider the benefits that will occur to the people and society and financial support from the state. In the spirit of the Constitution, the establishment of a consumer organization that is free and impartial is essential at the ground level. To perform the functions of the consumer's organization and for the maximum benefit of the people, the Thai legal framework requires enhancement.

The research found that Thailand does not have provisions to prescribe rules for protecting the rights and freedoms of the people. The protection of patent holder's rights, which has been damaged by the monopoly on drug patents, was found to not be protected. It is inconsistent with the theory of public law, the principle of protection of the rights and freedoms of the people, which are guaranteed by the Thai judicial system. This results in legal problems regarding the lack of rules. inaction to protect the rights and freedoms of those rights holders. This is extremely important for protecting people's right to consume drugs in Thailand.

Therefore, it was found that Thailand does not have provisions to prescribe rules for protecting the rights and freedoms of those whose rights have been damaged by the monopoly. The principle of contractual relationships had a profound impact on the right inconsistent with the concept and consumer protection. These principles are found to be affecting several copyright infringers to increase and they are not afraid of the law due to the inadequacies of the legal framework in Thailand. This causes the users of the law to use discretion in the interpretation, which is not the same standard as laid down in basic human rights and by the constitution of Thailand. Likewise, it adversely affects the preservation of intellectual property rights and the protection of the rights of those who have been infringed. This is enhanced by the absence of effective law because when the court has no norms or a standardized approach to law enforcement, consumer protection is challenged. Therefore, it comes out in the form of extending the seller's responsibility to other parties, but it cannot guarantee or ensure that it will always be satisfactory. This implies that the consumer of drugs is at risk, i.e., harm to health, body, or life caused by a monopoly on the drug. Similarly, without the quality and applicability of the universal standards, causes the state is unable to effectively provide protection and safety for the health, life, and body of the people and consumers of drugs. It also affects the people's right to exercise their rights in the justice system, which will lead to a lack of confidence in the judiciary, which serves to enforce the law.

Currently, cases involving intellectual property, whether trademark lawsuits, copyright infringement cases, patent infringement cases, or other types of intellectual property-related lawsuits, suffer from just execution. This is because the state's mechanism is not yet strong and the benefits of illegal marketing mechanisms have increased. As a result, the holders of intellectual property rights, whether copyright, patent, or other types of intellectual property, have been

infringed. It is found to be difficult to find evidence, whether it is a document or an object witness, that will be used to take the court. The criminal process involved in the infringement of copyright or intellectual property has a complex legal and technological mechanism in Thailand. It results in inaccuracies in providing evidence to show the court that the accused or the parties who committed an offense under the law relating to the intellectual property impact of accepting data exclusivity claims. Currently, legal protection covers only patented drugs. This poses a limitation on the data that is used for legal proceedings. This reduces the protection of the rights of non-patented drugs and their distribution in Thailand. The expected economic, social, and legal effects will be greater than the effects depicted in current government reports. However, how much such an effect increases will depend on the medicinal cost of the new, non-patent drug as well as upon the flexibility in the use of substitution (elasticity of substitution) between other drugs and the new drugs. From the results of the study, it was found that the effect of monopolizing drug patents has non-binding legal protection towards the right holders. Considering that it will adversely affect generic drugs being delayed entering the market, including how much the country's drug expenditure increases. In the event of a monopoly on drug patents, Thailand has been suffering from inadequate legal measures to ensure patented drugs and non-patented drugs are effectively distributed in the market.

Monte Carlo simulation is a method of understanding the situation simply by experimenting many times other when the exclusivity period increases, the delay in getting generic drugs on the market increases at an accelerated rate [37]. In the past, for the most part, it was found that allowing generic drugs to be released into the market was delayed. But if there is a monopoly on data for the period that appears in the EU-Vietnam Free Trade Agreement, it is found that it does allow generic drugs to be released into the market with a delay. This is required to be implemented by the patent holders' stakeholders at the governance level in Thailand.

However, the impact of drug patent protection (Data Exclusivity), the present act facilitating the approval of government officials (B.E. 2015) has helped the drug registration process to be more efficient. The regulations in Thailand aim at extending the patent life that has protected or monopolized the prototype drug market based on the patent life. But if Thailand has a drug patent protection agreement with the European Union, it will affect the period of market monopoly, which is a major concern important to Thailand's economic development.

The importance of protecting drug patents is derived from the principle that one important thing is that the state plays an important role in organizing an intellectual property system that does not cause striped incentives for research and development of the intellectual property. A study on market exclusivity loss affecting drug development has found that an increase in the loss of exclusivity reduces the probability of drug approval and the continuity of drug development [10], when considering the period of the patent that was not granted. Loss of patent protection in the early stages of product development has been found to have a significant negative impact important to commercial outcomes compared to recent and unapproved patents. Patent invalidation has different effects according to the size (small, medium, or large) of the originator companies, with large innovator companies abandoning projects after a reduction in the amount of time they expect to gain a monopoly. A good systematization must be able to encourage research and development incentives for the prevention of intellectual property infringements when placing the order. Selling new products in the market so that researchers or manufacturers can receive a return that is worth investing in both domestic and foreign production. Developing new drugs is a costly form of research, and development is at a very high level. and have to go through a long testing process. The process of clinical drug form for humans; preliminary includes the initial phase (Phase 0), which looks at safety when used in people for the first time (10–15 people), such as observing preliminary results. When human beings are exposed to severely used drug bites without therapeutic or diagnostic purposes.

Therefore, it can be seen that Thailand does not have any laws related to the process of importing medicinal compounds to produce generic drugs, especially in intellectual property cases. Instead, the provisions under the Civil Procedure Code shall apply *mutatis mutandis*. The basis of different judicial proceedings, therefore, affects the protection of legal rights for holders of copyright and intellectual property rights. This was found because the processes and procedures are not suitable for the urgent need in the drug registration process at effective. In each case relating to intellectual property for law enforcement and the protection of rights in the judicial process against the parties in both intellectual property cases. It also negatively affects the mechanism for the performance of duties by the state, which focuses on ensuring fairness to both parties in all cases [38]. There is also a problem with all forms of protection against intellectual property infringement. Determining the delayed step is, thus, unable to protect the rights of holders of intellectual property rights by the intent of the law.

At present, the enforcement of Thai intellectual property laws is a criminal measure coupled with a civil measure. Most rights owners wish to be compensated for civil damages for infringements of intellectual property rather than criminal penalties. especially patents related to medicinal inventions. It is a problem that has been around for a long time. However, the original purpose of providing notification of patent status when applying for drug formulary registration was to benefit of preventing patent infringement. This is beneficial for both the right pharmaceutical companies and drug manufacturers. Domestically, the presentation of documents only for a patent application for a drug that has been advertised does not provide any benefit to the prevention of patent infringement [39]. Reasons for how to query data

from a database. There is no clear designation for drug patent status, and delayed patent registration is caused by the problem of manpower of patent auditors at the Department of Intellectual Property is limited. As a result, the Department of Intellectual Property is unable to respond to the needs of service users who submit patent applications quickly [40]. In the past 20 years, the Department of Intellectual Property has only had 24 auditors, while the amount as many as 9,000 patent applications a year, resulting in an accumulated backlog of up to 36,000 applications, of which 12,000 were filed over five years.

The study results found that domestic drugmakers have a hard time planning drug research and development [41]. This included the potential for accidental infringement of patents. Patent status information for every patent application related to a drug-formulated product is therefore important and necessary for domestic drug research and development planning. However, a definitive drug patent status cannot be obtained by searching the database of the Department of Intellectual Property because the patent system uses English transliteration with the Thai language [42]. The translated name is not a generic name for a patented drug. A difficult and time-consuming search system requires special expertise. Therefore, it cannot be searched by English generic drug names, despite ongoing efforts to develop a patent database. When considering the law on how data is retrieved from databases of the Department of Intellectual Property.

SWOT Analysis: The following is the Strength, Weakness, Opportunity and Threat (SWOT) analysis for this research which explored various factors contributing to the ineffectiveness of the IP laws in Thailand.

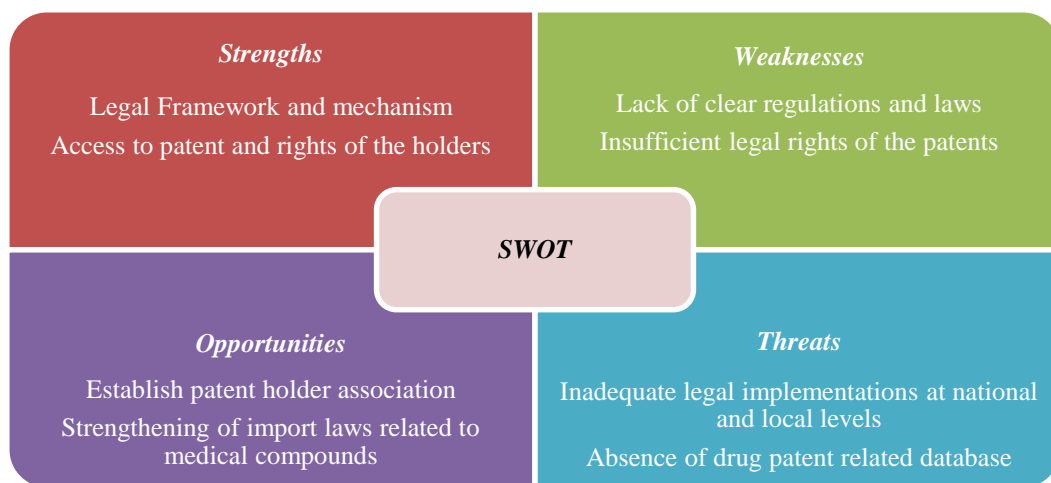


Figure 2. SWOT analysis for this research

The SWOT analysis has been carefully drafted along with the main findings of the research and a relative review of the existing documents. The SWOT has been coded to incorporate the CAME methodology and recommend the strategies thereof for an effective legal framework in Thailand.

Strengths: The strengths found in this research include the prevalence of the legal systems and framework, which are the basic requirements to provide for the implementation of legal and political governance. This has been coded as S1, implying the "legal framework and mechanisms" as a strength in Thailand. The research finds that the effectiveness of this existing system would provide adequate legal protection for patent rights holders.

The second code has been given to the strength as S2, implying "access to patents and rights of the holders". This shows that there is a mechanism existing for patent rights holders. However, accessibility is subject to governance and awareness generation at the domestic level, especially in rural and remote locations in Thailand.

Weaknesses: The major weaknesses found in the study have been coded into W1 and W2, implying "lack of clear regulations and laws" and "insufficient legal rights of the patents," respectively. This weakness acts as a barrier to the effectiveness of the already existing legal framework. The domestic law is in the Thai language, and all available translations are unofficial. The focused legal rights of the patent holders are limited due to unawareness and inaccessibility to the legal system.

Opportunities: There are several opportunities available for the protection of the patent rights holders, which were formulated through previous literature and experts' opinions. There are two of the most important opportunities selected and are coded as O1, depicting "Establish patent holder association" and O2, referring to "Strengthening of import laws related to medical compounds".

Threats: Despite the positive approaches by the stakeholders, the legal framework in Thailand fails to protect the rights of the patent holders. This is since local-level governance lacks adequate implementation of laws and regulations. Thus, the first threat has been coded as T1, referring to "inadequate legal implementations at national and local levels". Another threat is the lack of interest in maintaining the record and updating the drug-related information. This has been coded as a major threat T2, referring to the "absence of drug patent-related databases."

This coded SWOT analysis was provided to the Delphi panelists, who were requested to provide the ranking of each SWOT as a matrix to find the most significant factors. The Delphi panelists were selected randomly from the legal stakeholders involved in copyright and patent protection. These included judges, lawyers, government officials, NGO officials, and legal company representatives. This carefully selected panel provided an in-depth analysis of the SWOT and ground-level realities in Thailand. The hurdles, limitations, and critical analysis were carried out with the designation of scores for each code of the SWOT analysis.

The matrix scoring of strengths with opportunities and threats provides the most significant variable due to the highest scores. The results depict the significance of the legally binding framework needed to protect the patent holders. The CAME analysis provided for correcting the existing legal framework in Thailand, adapting the international patent holder's rights and guidelines to ensure adequate governance, maintaining justice in case of disputes arising out of violations of the legal rights, reducing the monopoly in the drug market, and exploring the implementation of the legal framework as well as the effectiveness of the system. The CAME analysis provided to enhance the legal framework through strategic implementation of patent rights holders and intellectual property rights at all levels of governance (Table 2).

Therefore, in Thailand, there are no statutory provisions relating to the fact that no clear drug patent status has been established. It will directly affect the protection of the rights of users who apply for patents in intellectual property cases. It also affects the protection of holders of intellectual property rights that are difficult to acquire. Furthermore, it causes litigation damage and has another impact on the private sector's business mechanisms related to intellectual property.

Table 2. Coding of SWOT through Delphi panel for CAME analysis

Coded SWOT	Opportunity 1	Opportunity 2	Threat 1	Threat 2
Strength 1	98	58	84	73
Strength 2	76	67	71	85
Weakness 1	83	64	96	72
Weakness 2	69	54	69	73

5- Discussion

Intellectual property rights have been a growing factor contributing to the sustainable development of several developing states [43]. However, the various aspects of IP, inclusive of copyrights, patents, and trademarks, are to be effectively legally binding to ensure the protection of the right holders [44]. IP protects the intellectually innovative ideas of the innovators and provides for the legal protection and economic benefits of the right holders [45].

The patent protection is under Article 27.1 of the TRIPS agreement and protects the patent holder's rights [46]. Under Articles 27.2 and 27.3, some of the members of the TRIPS agreement may be excluded from the patent rights as well. Therefore, the domestic law implications are higher than the international norms and legal guidelines. The domestic law is to be effective to ensure the protection of the rights of the right holder "*ordre public*" during the legally binding laws.

The following are three conditions where an invention is to be protected under the patent:

1. When a new invention has been invented.
2. There is a step of inventive nature in the innovation process.
3. The invention could be adopted in the industrial sector.

Therefore, the economic repercussions of the patented right holder's protection are of utmost importance. The larger public benefit is also to be analyzed as one of the major variables in the patenting of the new technological advancement. The *de facto* market exclusivity of the patented products must be implemented and protected under domestic laws. The legitimate interest emphasizes the social and economic interest in the patent, which resides with the demand and monopoly of the producers in the market. However, the Doha Declaration on the TRIPS agreement and Public Health provide for compulsory licenses for selective drugs in medical and pharmaceutical companies [47].

Similarly, during national emergencies and extremely urgent situations, such as COVID-19, the domestic governance within the state may result in the withdrawal of the protection of the patent right holder. Thus, Article 31(f) of the Doha Declaration provides for the protection of countries that are developing and unable to provide the manufacturing capacities of the patented drugs. One of the exemplary licensing cases, inter alia, is the Canadian government allowing the Apotex company to manufacture the TriAvir medicine for Rwanda beyond the patent capacities of GlaxoSmithKline and Boehringer Ingelheim. Thus, the ex officio action by the state is not sufficient to withdraw the rights of the patent holder, who is required to follow the standard administrative and legal procedures under the TRIPS agreement.

This study found hurdles to protecting patent holders under the inadequate legal framework. This was worsened during the COVID-19 scenario. Problems with the process of importing medicinal compounds to produce generic drugs

in the country and Intellectual Property Law Enforcement Issues about how to query information from the database were enhanced during the COVID-19 pandemic. There was no clear designation of drug patent status and updated information, even among government organizations and departments. However, in practice, obstacles were encountered in implementing preventive plans. This was found to be lacking, whether because the drafted action plan was not yet feasible under the COVID-19 context or because of the limitations of the budget, etc.

In addition, from the study results, it can be seen that many chapters of TRIPS have had an impact on Thailand's access to medicines through the drug research and development process. These include the international guidelines related to pre-sale permission, production, import distribution, and access to each right. Consequently, TRIPS can cause both positive and negative effects. At the same time, there is an opportunity to develop the system to be more efficient and transparent. Although the effect on access to medicines of TRIPS participation and study results has been currently less studied [48]. Globally, patent protection has shown a negative trend from TRIPS, and Thailand will likely need to prepare measures purpose to comply with the agreement, including TRIPS, such as improving the work system of the staff as well as changing the very relevant laws. However, there is still a lack of supporting information and governance, especially at the local level. This calls for a thorough study of the impact on access to medicines and the development of supportive measures to minimize those impacts [49]. International agencies, whether the World Health Organization (WHO), have campaigned that those countries participating in free trade negotiations should not accept proposals or agreements on intellectual property protection beyond TRIPS rights based on past empirical evidence. The protection of intellectual property at the TRIPS level is unclear whether it will have a positive impact on public health, where more than TRIPS may cause more harm than good.

The researcher agrees that further amendments should be made to the establishment of the Intellectual Property and International Trade Court Act and the Intellectual Property and International Trade Tribunal Act, B.E.1996. Laws should be enacted to make the main protection of intellectual property rights under international law, such as trade-related intellectual property rights agreements or agreements TRIPs (Agreement on Trade-Related Aspects of Intellectual Property Rights or TRIPs Agreement). It sets minimum standards for the protection of intellectual property rights, determines the right method, and has been effective in enforcing intellectual property rights. The implementation includes the prevention and resolution of disputes arising from violations of rights for the patent holders. However, they are found to be inadequate in the previous literature in terms of adequate implementation [31]. Articles 7 and 8 of the TRIPs Agreement clearly emphasize the objectives and fundamental principles of TRIPs for the member states to guide their implementation with the objective of protecting and enforcing intellectual property rights. This implementation should support the promotion of technological progress, transfer, and propagation of technology.

TRIPS and domestic law are essential for the mutual benefit of creators and users of information technology in a manner that leads to social and economic benefits. It was found that these laws assist in the balance between rights and duties other including taking reasonable measures to prevent the wrongful use of intellectual property rights by the rights owners or the unreasonable use of practices that result in trade barriers. It is detrimental to international technology transfer in the domestic drug market [38]. The National Drug Board's authority to bundle set criteria, methods, and conditions to control drug prices that are unfair to consumers and to control drug prices that are rational, transparent, and to be effectively enforced in Thailand. The department is responsible and must include prohibiting drug hoarding without reasonable reason to prevent a monopoly on the drug market and the inaccessibility of drugs belonging to the patient.

The research found that there should be a process for importing medicinal compounds to produce generic drugs in the country. This should be done in particular for intellectual property cases to avoid the need to apply the legal provisions of the Civil Procedure Code to such processes in intellectual property cases. It was deemed appropriate that there should be a draft of the provisions on Intellectual Property and International Trade Judicial Procedure (No....) for B.E. countries in particular intellectual property cases. This further deems it appropriate to propose alternatives to formulating drug price policies by arranging mechanisms for the National Drug System Development Board. These implications enhance duties in determining setting the price of the drug process by importing medicinal compounds to produce generic drugs throughout the supply chain. The Ministry of Commerce and the Department of Internal Trade carry out their duties to monitor and enforce the law for those who violate it and to control the price of drugs as announced by the National Drug Board.

The researcher agreed that there should be organized the database so that it can be searched easily and conveniently should be organized. The patent database is in three languages: Thai, English, and Mandarin [13] In the list of published drug patents, it should be clearly stated that they are relevant to the drug. Generic names or important drug names or trade names in English form make them easier to find and clearer. In addition, wish there was an updated notification system pointing to requiring the use of identical spellings in each patent form for the same drug list, especially the place important, such as the name of the drug or the name of the molecule, etc. The format should be improved to be more easily searchable, such as the European Patent Model or the Pharmacy Social Research Laboratory Model. Faculty of Pharmacy Chulalongkorn University, etc., which will be added to search topics such as (1) trade names, generic names, and drug groups to help increase the convenience of quickly searching for desired topics, or (2) specifying the status of

a patent. The remaining validity of the drug patent from the date of filing does drug patents for use in formulary development planning get that add a channel for wearing a search more to help search for more specific information add the topic "Patent Expiration Date" to the search selection. requires the name of the real owner of the product to be patented should the icon be clear or more easily noticed.

6- Conclusion

Thailand needs to set up an effective legal framework to ensure the protection of patent rights holders and adequate intellectual property rights. The drug monopoly must be replicated with the import of technological advancement and drug products. The international convention and declaration-based guidelines should be followed in terms of the Thai economy. The robustness of the legal framework in Thailand will ensure the safety of the patent rights holder and the protection of intellectual property rights. This scenario must be relevant in times of emergency, such as the COVID-19 pandemic. The preventive plans must be implemented despite the COVID-19 restrictions to protect the patent rights holders in Thailand. These regulations must be provided as awareness campaigns to all rights holders.

The study provides recommendations for the establishment of consumer and patent holder's rights protection organizations at the various levels of governance. This would be ensured through the establishment of consumer protection courts, litigation, and dispute-resolving bodies directly under the Thai legal framework. There must be a bar (legal body) for the legal stakeholders to be equipped with legal knowledge and licensing to protect against copyright infringements and patent violations. Another mandatory revision in the Act in Thailand must include an amendment related to the definition and scope of the legal terminologies, including monopoly and import restrictions for drug patent and right holders. These are required to be translated officially into the English language. The patent details and marketing advertisements under the direct supervision of the domestic legal framework must be implemented at the local levels as well. The research paves the way for future micro-level research into the considerations of ensuring intellectual property rights and effective protection of patent rights holders. This could be linked with business and disruptive event repercussion research. Similarly, studies may be conducted to ensure the economic and legal safety of the rights holders.

7- Declarations

7-1- Author Contributions

Conceptualization, W.P.; methodology, S.P.; software, S.P.; validation W.P.; formal analysis, W.P. and I.B.; investigation, W.P.; resources, W.P.; data curation, W.P. and S.P.; writing—original draft preparation, W.P.; writing—review and editing, W.P. and S.P.; visualization, W.P.; supervision, W.P.; project administration, W.P.; funding acquisition, W.P. All authors have read and agreed to the published version of the manuscript.

7-2- Data Availability Statement

Data sharing is not applicable to this article.

7-3- Funding

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7-5- Institutional Review Board Statement

Not applicable.

7-6- Informed Consent Statement

Not applicable.

7-7- Conflicts of Interest

The authors declare that there is no conflict of interests regarding the publication of this manuscript. In addition, the ethical issues, including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, and redundancies have been completely observed by the authors.

8- References

- [1] Adkisson, R. V. (2004). Intellectual Property Rights in the Global Economy. *Journal of Economic Issues*, 38(1), 281–282. doi:10.1080/00213624.2004.11506680.
- [2] Junod, V. (2004). Drug marketing exclusivity under United States and European Union law. *Food and Drug Law Journal*, 59(4), 479–518.
- [3] Reichman, J. H. (1996). From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement. *New York University Journal of International Law & Politics*, 29, 11.
- [4] Zappalaglio, A. (2022). Getting Article 22(1) TRIPS Right: A Commentary on the Definition of ‘Geographical Indication’ from a European Union Perspective with a Focus on Wines. *The Journal of World Investment & Trade*, 23(2), 180–217. doi:10.1163/22119000-12340246.
- [5] Braga, C. A. P., Fink, C., & Sepulveda, C. P. (2000). Intellectual property rights and economic development. World Bank Discussion Papers No. 412, World Bank Publications, Washington, United States.
- [6] Cavagnero, S., & Giordano, S. (2022). Sui Generis Geographical Indications Fostering Localized Sustainable Fashion: A Cross-Industry Assessment. *Sustainability (Switzerland)*, 14(9), 5251. doi:10.3390/su14095251.
- [7] Arunanondchai, J., & Fink, C. (2006). Trade in health services in the ASEAN region. *Health Promotion International*, 21(Suppl_1), 59–66. doi:10.1093/heapro/dal052.
- [8] Payyappallimana Unnikrishnan. (2010). Role of Traditional Medicine in Primary Health Care- An Overview of Perspectives and Challenges. *Yokohama Journal of Social Sciences*, 14(August), 57–77.
- [9] Tenni, B., Moir, H. V. J., Townsend, B., Kilic, B., Farrell, A.-M., Keegel, T., & Gleeson, D. (2022). What is the impact of intellectual property rules on access to medicines? A systematic review. *Globalization and Health*, 18:40. doi:10.1186/s12992-022-00826-4.
- [10] Yoongthong, W., Hu, S., Whitty, J. A., Wibulpolprasert, S., Sukantho, K., Thienthawee, W., Han, H., & Scuffham, P. A. (2012). National Drug Policies to Local Formulary Decisions in Thailand, China, and Australia: Drug Listing Changes and Opportunities. *Value in Health*, 15(1), S126–S131. doi:10.1016/j.jval.2011.11.003.
- [11] Ngorsuraches, S., & Chaiyakan, K. (2015). Equitable Prices of Single-Source Drugs in Thailand. *Applied Health Economics and Health Policy*, 13(4), 389–397. doi:10.1007/s40258-015-0165-6.
- [12] Niëns, L. M., & Brouwer, W. B. F. (2013). Measuring the affordability of medicines: Importance and challenges. *Health Policy*, 112(1–2), 45–52. doi:10.1016/j.healthpol.2013.05.018.
- [13] Kuanpoth, J. (2015). Intellectual property and transparency in trade negotiations: The experience of Thailand. *Journal of Intellectual Property Rights*, 20(2), 112–121.
- [14] Maskus, K. E. (1998). The role of intellectual property rights in encouraging foreign direct investment and technology transfer. *Duke Journal of Comparative & International Law*, 9, 109–161.
- [15] Puasiri, W. (2013). Patent Registration and Innovations in Thailand: Impediments or Improvements?. *Thammasat Review*, 16(1), 215–228.
- [16] Serebenjapol, P. (2010). Copyright perspectives from Thailand. *Community and Junior College Libraries*, 16(1), 37–46. doi:10.1080/02763910903479353.
- [17] Phimolsathien, T. (2018). Development of Guidelines for the System of Intellectual Property Management: Geographical Indication in Each Age Range. *Asian Administration & Management Review*, 1(1).
- [18] Forman, L. (2012). From TRIPS-Plus to Rights-Plus: Exploring Right to Health Impact Assessment of Trade-Related Intellectual Property Rights through the Thai Experience. *Asian Journal of WTO and International Health Law and Policy*, 7(2), 347–375.
- [19] Reichman, J. H. (2009). Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach. *SSRN Electronic Journal*. doi:10.2139/ssrn.1433392.
- [20] Haley, G. T., & Haley, U. C. V. (2012). The effects of patent-law changes on innovation: The case of India’s pharmaceutical industry. *Technological Forecasting and Social Change*, 79(4), 607–619. doi:10.1016/j.techfore.2011.05.012.
- [21] Daengprasert, S., Sutanthavibul, N., & Chandrachai, A. (2012). Development Process for Thai Traditional Medicines. *Journal of Medical and Bioengineering*, 1(1), 11–13. doi:10.12720/jomb.1.1.11-13.
- [22] Howard, L. (2009). Strategic use of Supplementary Protection Certificates (Part 1). *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector*, 6(3), 284–291. doi:10.1057/jgm.2009.18.
- [23] Kutik, S. (2019). Strategies for medicinal product SPCs in Europe. *Journal of Intellectual Property Law & Practice*, 14(6), 438–444. doi:10.1093/jiplp/jpz026.

- [24] Menell, P. S. (1999). Intellectual property: General theories. *Encyclopedia of Law and Economics*, 2, 129-188.
- [25] Dratler Jr, J., & McJohn, S. M. (2023). *Intellectual property law: Commercial, creative and industrial property*. Law Journal Press, New York, United States.
- [26] Chapman, A. R. (2002). The human rights implications of intellectual property protection. *Journal of International Economic Law*, 5(4), 861–882. doi:10.1093/jiel/5.4.861.
- [27] Kristin, D., & Dewi, C. T. I. (2022). The Dilemma in COVID-19 Pandemic: The Protection of Intellectual Property Rights or A Life? *Media Iuris*, 5(2), 189–206. doi:10.20473/mi.v5i2.34349.
- [28] Parra Santiago, J. I., & Camarero, A. (2020). Puesta en valor de infraestructuras logísticas con utilización de la metodología DAFO-Delphi-CAME. El caso de la plataforma logística ferroviaria de Albacete. *Ingeniería Y Competitividad*, 23(1). doi:10.25100/iyv.v23i1.9006.
- [29] Kiewnin, K., Boontantrapiwat, T., Sosom, J., Hongtumrong, M., Khunakorncharatphong, A., Kanchanachitra, C., & Pachanee, C. A. (2021). International trade and health in thailand: A scoping review. *International Journal of Environmental Research and Public Health*, 18(21), 11692. doi:10.3390/ijerph182111692.
- [30] Mitchell, A. D., Taubman, A. S., & Samlidis, T. (2023). Intellectual Property and Vaccine Manufacturing: Utilising Existing TRIPS Agreement Flexibilities for COVID-19 and other Public Health Crises. *Tulane Journal of Technology & Intellectual Property*, 25.
- [31] Nillsuwan, B. (2022). Imbalance Between Public Health and Intellectual Property Rights Protection Goals: Battles on AIDS Medicines in Thailand. *Globalisation and Local Conflicts in Africa and Asia. Evidence-Based Approaches to Peace and Conflict Studies*, 7, Springer, Singapore. doi:10.1007/978-981-16-8818-8_7.
- [32] Antons, C., & Blakeney, M. (2023). Intellectual property, creativity and innovation in ASEAN. *Intellectual Property Law in South East Asia*, 1-16, Edward Elgar Publishing, Cheltenham, United Kingdom. doi:10.4337/9781035308392.00005.
- [33] Garcia, G. (2023). Intellectual property rights in South East Asian least developed countries: The cases of Cambodia, the Lao Peoples Democratic Republic, and Myanmar. *Intellectual Property Law in South East Asia*, 175-215, Edward Elgar Publishing, Cheltenham, United Kingdom. doi:10.4337/9781035308392.00011.
- [34] Cuesta-García, A., Fernández-Lansac, V., & Crespo, M. (2023). Barriers to access intimate partner violence services in female Romanian immigrants in Spain: A Delphi study. *Journal of Community Psychology*, 51(1), 297–318. doi:10.1002/jcop.22904.
- [35] Peterson, E. (2018). Techniques for Addressing Managerial Attitudes toward Lawyers and the Law. *Southern Law Journal*, 28(1), 1-25.
- [36] Sánchez-Cambronero, A., González-Cancelas, N., & Serrano, B. M. (2020). Analysis of port sustainability using the PPSC methodology (PESTEL, Porter, SWOT, CAME). *World Scientific News*, (146), 121-138.
- [37] Kosmidis, K., Argyrakis, P., & Macheras, P. (2003). A reappraisal of drug release laws using Monte Carlo simulations: The prevalence of the Weibull function. *Pharmaceutical Research*, 20(7), 988–995. doi:10.1023/A:1024497920145.
- [38] Napaporn, J., Buakaew, P., Suksakornthanawat, P., Sripan, S., Jinatongthai, P., & Supapaan, T. (2022). Analogous comparison of registered brand name drugs of tablets and capsules commercially available in Thailand: A retrospective study. *PLOS ONE*, 17(10), e0276321. doi:10.1371/journal.pone.0276321.
- [39] Wongburanavart, A. (2023). Traditional Knowledge and Intellectual Property Protection: Challenges and Opportunities in Thailand. *The Journal of Law, Public Administration and Social Science. School of Law Chiang Rai Rajabhat University*, 7(1), 47-71.
- [40] Motohashi, K. (2020). Development of patent database in Thailand for assessing local firms' technological capabilities. *World Patent Information*, 63, 101998. doi:10.1016/j.wpi.2020.101998.
- [41] Ray, A., Tripathi, S., & Rai, A. (2019). Pharmaceuticals Export and Market Evolution in India and Thailand. *Trends in Biosciences*, 12(1), 1–20.
- [42] Drahos, P. (2008). "Trust me" Patent offices in developing countries. *American Journal of Law and Medicine*, 34(2–3), 151–174. doi:10.1177/009885880803400205.
- [43] Sinnreich, A. (2019). *The Essential Guide to Intellectual Property*. Yale University Press, New Haven, United States. doi:10.2307/j.ctvgc628g.
- [44] Zermeño-Guerrero, J., Garza-Ruiz, M., & Rodríguez-Padilla, M. C. (2021). Knowledge on intellectual property as an advantage for scientific research. *Inquietud Empresarial*, 21(1), 103–116. doi:10.19053/01211048.11533.
- [45] Ding, Q., Gao, S., Zhu, J., & Yuan, C. (2020). Permissioned Blockchain-Based Double-Layer Framework for Product Traceability System. *IEEE Access*, 8(5), 6209–6225. doi:10.1109/ACCESS.2019.2962274.

- [46] Correa, C. M. (2005). Implementing the Trips Agreement in the Patents Field. *The Journal of World Intellectual Property*, 1(1), 75–99. doi:10.1111/j.1747-1796.1998.tb00004.x.
- [47] Elnaïem, A., Mohamed-Ahmed, O., Zumla, A., Mecaskey, J., Charron, N., Abakar, M. F., Raji, T., Bahalim, A., Manikam, L., Risk, O., Okereke, E., Squires, N., Nkengasong, J., Rüegg, S. R., Abdel Hamid, M. M., Osman, A. Y., Kapata, N., Alders, R., Heymann, D. L., ... Dar, O. (2023). Global and regional governance of One Health and implications for global health security. *The Lancet*, 401(10377), 688–704. doi:10.1016/s0140-6736(22)01597-5.
- [48] Ritter, A. (2009). How do drug policy makers access research evidence? *International Journal of Drug Policy*, 20(1), 70–75. doi:10.1016/j.drugpo.2007.11.017.
- [49] McBride, D. C., Terry-McElrath, Y., Harwood, H., Inciardi, J. A., & Leukefeld, C. (2009). Reflections on drug policy. *Journal of Drug Issues*, 39(1), 71–88. doi:10.1177/002204260903900107.