

16. THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS FOR PHARMACEUTICAL INVENTIONS IN VIETNAM

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ABSTRACT

Vietnam is a Southeast Asian country with a developing economy. The need for medicine to cure diseases and to enhance general health is among many heated social issues in Vietnam. However, this need faces multiple barriers, including intellectual property rights to pharmaceutical inventions of domestic and foreign owners, which is a requirement of several international treaties in which Vietnam has participated. Striving for balance between protecting intellectual property rights to pharmaceutical inventions and people's right of access to medicines has always been a controversial matter at a worldwide scale, but it is still a new concept in Vietnam.

This paper focuses on analysing the effects of Vietnamese law on the protection of intellectual property rights of pharmaceutical inventions by presenting the international commitments that Vietnam has made

concerning these rights. This paper also presents the current practice of registering and protecting intellectual property rights to pharmaceutical inventions in Vietnam, and possible solutions to improve regulations and cooperation systems while balancing the patent owner's intellectual property rights to pharmaceutical inventions and peoples' right of access to medicines.

Keywords: *pharmaceutical patents, Vietnamese IP law, public health, access to medicines*

1. INTRODUCTION

For ages, pharmaceutical products have been man's indispensable weapon in the fight against diseases. The use of pharmaceutical products, including medicines, is a necessary demand for the existence of humankind. The Universal Declaration of Human Rights 1948, proclaimed by the United Nations General Assembly, asserts that the right to protect health is a basic human right, which includes the right of access to pharmaceutical products.¹ However, with the development of science and technology, another arising problem is the protection of intellectual property (IP) rights to inventions, including pharmaceutical inventions, since an intellectual property

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¹ Universal Declaration of Human Rights (1948) art 25, 'Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services'.

Similarly, the Constitution of the World Health Organization (WHO), enacted in 1946, stipulates the following:

'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition'.

The content of Article 25 of Universal Declaration of Human Rights 1948 and the Constitution of the World Health Organization (WHO), enacted in 1946 has been further elaborated in many international treaties on human rights, such as the International Covenant on Economic, Social and Cultural Rights (Article 7, 11, 12), articles 11.1 (f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women, article 24 of the Convention on the Rights of the Child, article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination, Article 23, 43 (e), 45 (c) of the International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families, Article 25 of UN Convention on the Rights of Disabled Persons.

right is also recognized as a basic human right to be respected. Regarding laws on intellectual property rights, the owner of the patent has the right to prevent others from using their invention or selling pharmaceutical products containing the invention because they can sell pharmaceutical products manufactured from a patent-protected method at high prices to fund subsequent research and development, as well as to gain profit. '[Patents] have a direct impact on prices for pharmaceutical products that affect equality of opportunity to access basic life-saving medicines.'² Therefore, the protection of intellectual property rights to pharmaceutical inventions, both under domestic and international legal frameworks, contains an imminent threat of conflicting with the right of access to pharmaceutical products and healthcare of people.

For the aforementioned reasons, many countries in the world do not have any protection, or are still considering protection for subject matter affecting public interest, including pharmaceutical products. This is because the extent to which the 'world's welfare' is influenced by international IP standards ultimately can only depend on choices and actions taken at the municipal level operating under domestic laws and legal measures. Municipalities mediate and interpret the standards in such a way that either delivers or denies the 'articulated standard of welfare.'³ However, in Vietnam, pharmaceutical inventions are always under intellectual property right protection. Because legal regulations for this controversial subject matter are scarce, the research about Vietnamese law on intellectual property rights to pharmaceutical inventions is indeed the research about Vietnamese law on intellectual property rights to inventions in general.

In Vietnam, invention patents began in 1981 by the issuance of Decree No. 31/CP: Regulations on Innovations of Technological Improvement and Rationalization of Production and on Inventions dated 23 January 1981. This is the first legal document in Vietnam regulating the protection of inventions. According to this decree, Vietnam protects industrial property rights in general (including pharmaceutical inventions) under two forms: Copyright or Patent. Several provisions of this Decree were amended pursuant to the Decision of the Council of Ministers No. 92/HDBT. In 1998, the Council of Ministers issued Decree No. 201-HDBT: Regulations on Selling and Purchasing of Use Rights of Inventions, Utility Solution, Industrial Design, Trademark and Technical Know-how (Regulations on Licensing). It can be observed that, during this period, there were only by-law instruments to regulate issues relating to inventions and other subject matters of industrial property rights lacking an official and comprehensive law. These instruments mostly dealt with the administration by related governmental bodies of issues relating to inventions.

In 1989, the Ordinance on Protection Industrial Property Rights (28 January 1989) was passed by the Council of State, replacing the aforementioned Regulations on Innovations of Technological Improvement and Rationalization of Production and on Inventions. After that, in 2000, the Council of Ministers issued Decree No. 84/HDBT to amend a variety of previous decrees, including the aforesaid Decree No. 201-HDBT Regulations on Selling and Purchasing of Use Rights of Inventions, Utility Solution, Industrial Design, Trademark and Technical Know-how. Until this time, the protection of industrial property rights had deviated in nature with that of the previous centrally planned economy. The industrial

² Carsten Fink, *Intellectual Property and Public Health: An Overview of the Debate with a Focus on US Policy - Working Paper 146* (2008) <<https://www.cgdev.org/publication/intellectual-property-and-public-health-overview-debate-focus-us-policy-working-paper>> accessed 24 May 2019.

³ Antony Taubman, 'TRIPS Jurisprudence in the Balance: Between the Realist Defence of Policy Space and a Shared Utilitarian Ethic' in Christian Lenk, Nils Hoppe and Roberto Andorno (eds), *Ethics and Law of Intellectual Property. Current Problems in Politics, Science and Technology* (Ashgate 2009) 117.

property rights subject matters were the product of a market economy. At this time, Vietnam adopted legal documents recognizing private ownership of inventions as well as other subject matters of industrial property rights. Unlike the previous period, inventions then could only be protected under the form of 'Patent.'

On 28 October 1995, the Civil Code of the Socialist Republic of Vietnam was passed by the ninth National Assembly at its eighth session, and came into effect on 1 July 1996. Several provisions of this Code regulate the protection of industrial property rights and became the legal source with the highest effect for the protection of intellectual property rights, including intellectual property rights to pharmaceutical inventions. The Civil Code then was the basis for protection of the subject matters of industrial property rights and also an achievement of codification. The legal framework on the protection of intellectual property rights continued to develop, existing principles continued to be finalized. Together with the Civil Code of 1995, a variety of by-law instruments were issued; as Decree No. 63/CP specifying industrial property rights, Decree No. 12/1999/ND-CP on Sanctioning of Administrative Violations in Industrial Property, and the circulars guiding implementation.

From the demands of negotiation for accession to WTO and other objective needs, Vietnam has made great efforts in amending the law on intellectual property, with a view of meeting the minimum requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). At the same time, Vietnam is fully utilizing the exceptions to balance between the benefits

of intellectual property owners and of society. The issuance of the Law on Intellectual Property of 2005 (IP Law of 2005), amidst the integration trend and international commitments of Vietnam including TRIPS, has created a relatively complete legal framework to protect intellectual property rights, including inventions and pharmaceutical inventions. Together with the IP Law, various by-law instruments were also issued to provide instructions on the IP Law of 2005.⁴ Most recently, the IP Law in 2005 has been amended by Law No. 36/2009, with some supplemental provisions, including ones on pharmaceutical inventions.

Besides the IP Law of 2005, a wide array of legal documents in related legal fields also provide a pivotal legal basis for the implementation of intellectual property rights to inventions. These documents include the Civil Code of 2015, the Civil Procedural Code of 2014, the Criminal Code of 2000, the Ordinance on Sanctioning of Administrative Violations of 2002, the Law on Customs of 2001, the Law on Enterprises of 2014, the Commercial Law of 2005, and the Competition Law of 2004. Besides general provisions on the protection of inventions, there are the provisions specialized for pharmaceutical inventions such as the Law on Pharmacy No. 34/2005/QH11, Circular No. 22/2009/TT-BYT on registration of drugs (with the whole Chapter II focusing on intellectual property rights to registered drugs), Circular No. 05/2010/TT-BYT guiding the Confidential Protection of Trial Data in Drug Registration, and Circular No. 09/2010/TT-BYT guiding the Management of Drugs Quality.

⁴ World Intellectual Property Organization (WIPO), decree 103/2006/ND-CP, 22 Sept. 2006, detailing and guiding the Implementation of several Articles of the Law on Intellectual Property regarding Industrial Property:

- WIPO Circular No. 01/2007/TT-BKHCHN guiding the Implementation of the Decree No. 103/2006/ND-CP;
- WIPO Decree No. 122/2010/ND-CP amending and supplementing a number of Articles of Decree No. 103/2006/ND-CP;

- WIPO Decree No. 105/2006/ND-CP detailing and guiding the Implementation of a number of Articles of the Law on Intellectual Property on Protection of Intellectual Property Rights and on State Management of Intellectual Property;
- WIPO Decree No. 97/2010/ND-CP on Sanctioning of Administrative Violations in Industrial Property.

2. PROTECTION OF IP RIGHTS FOR PHARMACEUTICAL INVENTIONS ACCORDING TO THE INTERNATIONAL COMMITMENTS OF VIETNAM

In many international negotiations on IP protection of pharmaceutical inventions, the main concern of parties revolved around, (i) the enhancement of protection level and the rights of the invention owner; and (ii) the desire for better public health by keeping the availability of drugs at a reasonable price.

The Paris Convention, the first international treaty on industrial property rights protection, is an important guideline for citizens of the contracting parties to ensure IP rights protection in the other member states' territory. Under the Paris Convention, the member states have an obligation to protect inventions in all fields of technology. In the final rounds of discussion and the final draft, participating countries mutually agreed to establish a flexible regulation on a protection regime towards the subject matter of IP protection affecting significantly the public health (including pharmaceutical inventions). It is the regulation on compulsory license.⁵ The countries, particularly developing countries like Vietnam, want to maximize the advantage of this regulation, thanks to its flexibility, the exclusiveness of patent owners in using products bearing IP protection subject matter could be reducing for the reason relating to public health, and for the demand of prevention and cure of diseases.

Turning to TRIPS, inventions in the pharmaceutical industry attracted more attention and became a hot issue when the protection requirements became more specific. For example, there have been several regulations relating to the pharmaceutical industry. Article 27 of TRIPS stipulates that the contracting parties shall have an obligation to grant a patent for any invention in any field of technology; therefore, inventions in the pharmaceutical industry shall not be excluded from this article. By regulating patents available in any field of technology, TRIPS resolved the most controversial issue during the negotiation rounds, the scope of protection for the invention. This regulation of TRIPS seemed to be a concession of the developing countries and a success of the developed ones, especially the United States in the negotiation of TRIPS. The negotiations ended with a regulation that the contracting parties shall commit to protect inventions in all fields of technology provided they fulfil the requirements.

However, during the implementation of TRIPS, regulations with a higher protection standard and a wider protection scope for the pharmaceutical industry caused many difficulties for developing countries. WTO member states therefore had to gather together to discuss and establish the Doha Declaration on the TRIPS agreement and Public Health (Doha Declaration). The Doha Declaration is a solution for concerns on public health in the TRIPS agreement. This declaration affirms the

⁵ Paris Convention for the Protection of Industrial Property, art 5
'(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
(3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.'

sovereign right to take measures to protect public health, such as granting compulsory licenses and parallel importation from contracting parties. The Doha Declaration also extended the transition period for Least-Developed Countries for the refusal of patent invention in the pharmaceutical industry to the year 2016.⁶ This declaration seems to be an initial success for developing countries because it provides a clear guideline for such countries to make their own decisions on the implementation of public health policy and reduce the effect of the patent system on their socio-economic conditions.

Since TRIPS was established, there has been no international treaty that draws more attention and is more widely circulated than the Trans-Pacific Strategic Economic Partnership Agreement (TPP) with only 12 contracting parties. After a five-year negotiation, the countries finally gathered together and signed the TPP in New Zealand on 04 February 2016. The TPP agreement is a second-generation trade agreement with an aim of building up a free market for Asia-Pacific countries. TPP covers around 40% of the global economy, and will

establish a new Pacific economy by lowering trade barriers for most commodities such as beef, dairy products and textiles, and will establish new standards and rules on investment, environment, and labour. Thus, this is the largest regional free-trade agreement officially signed. Regarding the pharmaceutical industry, the most controversial issue during the negotiation rounds was that the TPP finally set out a standardized framework for IP rights protection to a high and comprehensive extent. The TPP basically cured some drawbacks in previous international treaties on IP relating to the pharmaceutical industry.

After his inauguration, United States President Donald Trump signed an order withdrawing from TPP; as a consequence, the TPP could not be ratified. However, on the sidelines of the November 2017 Asia-Pacific Economic Cooperation (APEC) Summit in Danang, Vietnam, the TPP Ministerial Meeting was organized. The Ministers negotiated on pushing ahead the TPP deal in a new situation. On the grounds of the negotiations, the Ministers of 11 countries expressed their persistence in pursuing the proposed pathway, they made an

⁶ WTO, Declaration on the TRIPS Agreement and Public Health (2001)

<<http://www.who.int/medicines/areas/policy/tripshealth.pdf>> accessed 24 May 2019

'5. (...) (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.'

...

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.'

agreement on the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

In comparison to the TPP, around 20 articles of the CPTPP have been temporarily postponed, mainly the articles on intellectual property. For example, regulations relating to inventions in the pharmaceutical industry have been suspended, including patent term extension for patent office delay, patent term adjustments for unreasonable granting authority delay, protection of undisclosed test or other data and so on. The reason for this suspense is that the United States promoted most of these regulations and the other countries, including Vietnam, made concessions to reach a mutual agreement. In the context of the United States' withdrawal from the TPP, the remaining 11 countries stuck to their purpose of establishing a comprehensive agreement in which the benefits of contracting parties will be balanced based on the development ability of each country. Moreover, the TPP-11 will be maintained in a high-standard and comprehensive manner on all fields besides market-opening, trade and economy. With that mindset, regarding the postponement clauses, CPTPP is an innovative step in economic integration for members, especially for Vietnam, which is released from the strict regulations of intellectual property rights protection.

3. PROTECTION OF IP RIGHTS FOR PHARMACEUTICAL INVENTIONS UNDER DOMESTIC LAW OF VIETNAM

A. DEFINITION

The Domestic law of Vietnam does not directly stipulate any definition on 'invention relating to pharmaceuticals (pharmaceutical invention).'⁷ In accordance with the provisions of IP law and pharma-related documents, such as the Law on Pharmacy of 2005, the subject matter that is patentable can be defined in the pharmaceutical industry. Accordingly, *pharmaceutical inventions are patentable subject matter, including products or*

manufacturing processes applying to resolve problems in public health.

The pharmaceutical inventions can be divided into 2 categories:

(1) Product inventions include chemical compounds (used to make medicine), new forms of a known compound (isomer, salt, etc.), combined (mixed) compounds of given products/compounds, and special forms of pharmaceutical extract liquid.

(2) Process (method) inventions include chemical compound preparation processes, medicine preparation processes, and pharmaceutical extract process

B. SCOPE AND CONDITIONS FOR PROTECTION

A pharmaceutical invention is a protectable subject matter in Vietnam. Pursuant to IP Law article 59, pharmaceuticals and pharmaceutical manufacturing processes are protected in Vietnam because they do not fall into the list of objects ineligible for protection as invention. The conditions for pharmaceutical inventions are similar to that for the inventions in other fields. For example, a pharmaceutical invention shall be protected as an invention under a patent if it satisfies the worldwide novelty, inventive nature and is susceptible to industrial application.⁷

Firstly, the pharmaceutical invention shall meet the requirement of 'novelty'. Under the law of Vietnam, an invention shall be deemed novel if it has not yet been publicly disclosed. That means, a limited number of people could know and have the obligation to keep secret about this invention, by use or by means of a written description or any other form either inside or outside Vietnam before the filing date or the priority date, as applicable, of the invention registration application.⁸

Secondly, the pharmaceutical invention shall be 'an inventive step.' An invention shall be deemed to be of an

⁷ Law on Intellectual Property No. 50/2005/QH11 (IP Law).

⁸ *ibid* art 60.

inventive nature if, based on technical solutions already publicly disclosed by use or by means of a written description or any other form either inside or outside Vietnam, prior to the filing date or the priority date as applicable of the application for registration of the invention; the invention constitutes an inventive progress and cannot be easily created by a person with average knowledge in the art, and the art herein is pharmaceutical industry. Between the technical solutions already publicly disclosed, the significant progress shall be deemed to be the nature of an invention.⁹

Third, the pharmaceutical invention shall be susceptible of industrial application. An invention shall be deemed to be susceptible of industrial application if the information about the nature of the solution and instruction of required technical conditions is presented in a clear and comprehensive manner, to enable the person having an average level of knowledge in the pharmaceutical industry to be able to generate, produce, or be able to use, exploit, or carry out that invention or repeated application of the invention which is the subject matter of the invention, and to achieve stable results as determined in the application. The production, use, and exploitation of such solutions may be repeated with the same result and in the same manner as the results stated in the application. The law of Vietnam stipulates that an invention shall be deemed to be susceptible of industrial application if it is possible to mass manufacture the product and repeat the application process, which is the subject matter of the invention, and then to achieve stable results.¹⁰

C. TERM OF PROTECTION

Under TRIPS, the term of protection for invention shall not end before the expiration of a period of twenty years from the filing date. Members that do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant. The pharmaceutical invention shall apply

this term of protection as inventions in other areas of technology. So, the pharmaceutical invention shall be protected under a patent from the filing date to the end of the 20-year period.

This provision of TRIPS is necessary and suitable in actual context. Due to the inconstant development of technology, the life span of technological devices shortens and most of the devices are developed based on the given technology. When the technology was used for a period utility, the owner collected his necessary investment fee and gained benefits at a certain extent. Therefore, it must be released for everyone to use and enjoy its exceptional features.

Complying with the term of protection under TRIPS, the law of Vietnam, pursuant to Article 93 of the IP Law, states an invention patent shall be valid from the grant date until the end of twenty years after the filing date. Besides, it could be protected as a utility solution from the grant date until the end of ten years after the filing date. Thus, the term of invention protection is twenty years, fixed and not extended (the law does not allow the extension of protection term for the pharmaceutical invention).

D. RIGHTS AND OBLIGATION OF THE PATENTEE

First, the owner of a patent for a pharmaceutical invention shall have the right to use or authorize others to use his inventions. The usage and commercial exploitation of inventions brings many benefits to the owner and it can be seen as a powerful and the most important of the owner's rights. In fact, there are many different ways to exploit the right to use the pharmaceutical invention. The main ways of using a pharmaceutical invention are manufacturing pharmaceuticals: application of a patented process for manufacturing a pharmaceutical product; exploiting the utility of the protected pharmaceuticals or pharmaceuticals produced under the protected process;

⁹ *ibid* art 61.

¹⁰ *ibid* art 62.

the act of circulation, advertising, offering, storing for the circulation of pharmaceutical products; and the importation of pharmaceutical products protected as inventions or pharmaceuticals produced under the protected process in the name of invention.

During the term of protection, on the one hand, the patent owner has the right to use the pharmaceutical invention in his possession, production, or business activities, to benefit from such invention. On the other hand, the patent owner may also transfer the right to use a pharmaceutical invention to another entity by signing a contract for the use of an industrial property object, in writing and in accordance with laws on civil and economic contract.

Second, the owner of the pharmaceutical invention has the right to prevent others from using industrial property objects. During the term of protection, the owner is protected to gain benefits from his invention; it also means the owner has the right to prevent others from using his invention without any prior acceptance. Everybody shall have the obligation to respect and not to commit acts of harassment or infringement when the owner exercises his right to use. If there is an act of infringement of the owner's rights, the law recognizes the owner can take measures to protect his rights, such as self-protection, civil, border control, or administrative measures.

Third, the owner has the right to dispose of industrial property objects. Under the applicable law of Vietnam, the right to dispose of the pharmaceutical invention can be carried out under different ways. For example, this can be done by transferring ownership to others under a written contract; declaring relinquishment of the industrial property rights; inheriting others (by will or by law) after death; and transferring of rights according to the merger, consolidation, division, separation of legal persons.

Besides the provisions on the rights of the owner, the law also states the obligations the owner must comply with.

First, the owner of a pharmaceutical invention has the obligation to respect the regulations and limitations of rights for the pharmaceutical invention's owner. The rights of the invention owner allow them to prevent the others from using and exploiting the protected invention. However, as understood in the characteristics of this type of subject matter, this subject matter has a great influence on the interests of the community, rather than other objects of industrial property rights. So, the limitations imposed on the rights of the owner are generally set primarily for this subject matter. For this reason, the law provides certain exceptions that other persons may use or exploit the protected pharmaceutical invention without the consent of the patent holder or the licensee, by a license agreement, and it does not constitute an illegal action.¹¹ For example: using inventions in service of personal needs, for non-commercial purposes, for purposes of evaluation, analysis, research, teaching, testing, trial production or information collection for carrying out procedures of application for licenses for production, importation or circulation of products, or circulating, importing, exploiting utilities of products which were lawfully put on the market including overseas markets using inventions for maintaining the operation of foreign means of transportation transiting or temporary staying in the territory of Vietnam. Regarding the above circumstances, on one hand, the user does not have to obtain the permission; on the other hand, the law of Vietnam also stipulates that if the use of the invention is not for business purposes, no remuneration shall be paid to the owner of the invention.

Second, the law of Vietnam regulates the other obligations of a pharmaceutical patent holder. The owner shall have the obligation to use the protected invention, specifically, the owners shall be obliged to manufacture

¹¹ *ibid* art 125.12.

protected products or apply protected processes to satisfy the requirements of national defence and security, disease prevention, treatment and nutrition of the people, or to meet other social urgent needs. When the needs stipulated in this clause arise but an invention owner fails to perform such obligation, the competent State body may license such invention to others without permission from the invention owner. Additionally, the invention owner is obligated to authorize the use of original inventions when satisfying the two following requirements: (i) where the owner of a dependent invention can prove his or her invention makes an important technical advance as compared with the original invention and has great economic significance; and (ii) where the owner of a dependent invention negotiates with the owner of an original invention about a reasonable price and commercial conditions.

E. INFRINGEMENT AND ENFORCEMENT OF RIGHTS TO INVENTIONS

The IP laws of Vietnam do not regulate the acts of infringement of IP rights to each industrial property object. The act of infringement on rights to inventions, including pharmaceutical inventions, shall be generally determined pursuant to IP Law, Article 126. This article regulates the infringement of rights to inventions, industrial designs and layout designs. Furthermore, under Decree No.105/2006/ND-CP, the act of infringement of IP rights are the acts of infringement of rights to protected objects. Accordingly, the act of infringement of rights to pharmaceutical inventions are the same as rights to pharmaceutical invention within its protection term. Specifically, the act of infringement of rights to pharmaceutical invention includes two basic components:

- Using pharmaceutical inventions within the valid term of a protection title without permission from the owners.
- Using inventions without paying compensation, according to the provisions on provisional rights.

Based on the determination of acts of infringement of rights to pharmaceutical inventions, the law of Vietnam has established an enforcement system to protect the rights of pharmaceutical inventions' owners against the acts of other persons within the valid term of a protection title, such as civil, administrative, or temporary measures or border control. Moreover, IP laws also note another remedy to infringement - self-protection. Self-protection is regulated by the principles of respect and the protection of the civil rights in the Vietnamese law, recognized in Article 19 of the Civil Code and specified in Article 198 of the IP Law. Accordingly, the owner of the inventions can take action to protect his rights. The specific measures to be carried out are: (1) to apply measures to prevent acts of infringement of its intellectual property rights; (2) to request any organization or individual who commits an act of infringement of the intellectual property rights of the holder to terminate such act, make a public apology or rectification; and (3) to request the competent authority, including courts and arbitrations to protect his intellectual property rights.

4. STATUS OF PROTECTION OF IP RIGHTS FOR PHARMACEUTICAL INVENTIONS IN VIETNAM

A. REGISTRATION AND GRANT OF PROTECTION FOR PHARMACEUTICAL INVENTIONS

As mentioned above, a pharmaceutical invention is always considered protected under Vietnamese law. Thus, compared with other countries in the world, the laws of Vietnam in the field of intellectual property and patent protection is relatively new. It also can be admitted, however, that the protection for pharmaceutical invention was first mentioned when new IP regulations were introduced. On the basis of the first document on invention, the Charter of Technical Innovation - Rationalization of Production and Inventions dated 23 January 1981, the first application for invention was filed on 20 October 1984 with the registration number 1-1984-00064. This invention is called 'Method for preparation of diosgenin' and the applicant is the

National Institute of Medicinal Materials of the Ministry of Health. This application was granted patent No. 22 and was the first patent granted to a pharmaceutical invention.¹² Prior to the Civil Code of 1995, patent protection regulations were not systematically codified, the number of applications for pharmaceutical invention was low (32 applications), mainly submitted by domestic organizations and individuals and most of the applications involved traditional medicine.

The Civil Code of 1995 milestone marked the promulgation of Vietnam's first Civil Code, along with the development of a market economy. When Vietnam joined the Patent Cooperation Treaty (PCT), the number of pharmaceutical invention applications increased sharply. It is noted that applications were filed mainly by foreign companies (accounting for more than 90% of the applications related to pharmaceuticals).

Since the promulgation of the IP Law in 2005, and over a period of more than a decade, the registration of inventions generally progressed positively, despite many fluctuations. The number of patent applications filed to the National Office of Intellectual Property increased steadily from 516 in 2005 to 838 in 2015 (62.4%) and 1,028 in 2017. By the end of December 31, 2017, according to statistics of the National Office of Intellectual Property, the total number of applications for industrial property registration had been 57,962 applications, 1,028 patent applications, increased by 11% compared with 2016 (926 applications). Among these applications, 346 were applications for pharmaceutical inventions, which accounted for about 29% of the total number of patent applications. In particular in 2015, the number of pharmaceutical patent applications rose to a peak of 838 in comparison with 682 applications in 2014,

registering a 22.9% increase. The total number of protection titles issued in 2017 was 20,763 (an increase of 2,022 titles compared to 2016), 409 patents (increase of 33 patents from 2016), in which the patents in the field of pharmaceuticals is 158 patents, representing 38%.¹³

However, out of the total number of applications and patents in the field of pharmaceuticals, the majority of applicants and the number of issued patents, by origin of applicants, are mainly foreigners. Meanwhile, the number of Vietnamese applicants, as well as the number of issued patents for Vietnamese applicants, account for only a small portion of the total granted

Therefore, the pharmaceutical industry in Vietnam is becoming an attractive market for foreign pharmaceutical companies while the R&D capacity of domestic pharmaceutical companies is still very low and their competitiveness is not high.

The pharmaceutical industry in Vietnam is not paid much attention; pharma-chemical technology in Vietnam is classified in the weak group in the world due to backward technology. The Government of Vietnam has a plan to develop the pharma-chemical industry in order to meet 40% of antibiotic material demand for domestic production by 2020. However, according to current statistics, some projects for the Ministry of Industry on manufacturing raw materials for pharmaceuticals (such as Celphalosporin) have been stalled due to inefficient operation.¹⁴ Besides the technology, the pharmaceutical industry of Vietnam has had many other difficulties in developing, in which financial and legal barriers play an important role. The cost of producing a new active pharmaceutical ingredient is very expensive, about 100 billion VND, while the budget for research of the State, as

¹² National Office of Intellectual Property, *Annual Report of Patent Office* No. 2.

¹³ National Office of Intellectual Property, *Annual Report 2017*, <[http://www.noip.gov.vn/web/noip/home/vn?proxyUrl=/noip/cms_vn.nsf/\(agntDisplayContent\)?OpenAgent&UNID=8B950C5DCA92FB4447258300002BB1DF](http://www.noip.gov.vn/web/noip/home/vn?proxyUrl=/noip/cms_vn.nsf/(agntDisplayContent)?OpenAgent&UNID=8B950C5DCA92FB4447258300002BB1DF)> accessed 14 August 2018.

¹⁴ Drug Administration of Vietnam, *Annual Report 2016* <http://jahr.org.vn/downloads/JAHR2016/JAHR2016_full_VN.pdf> accessed 10 November 2018.

well as that of companies, is very limited. Now the legal framework for researching and testing of drugs in humans in Vietnam has not been fully built, so the testing faces a lot of difficulties. This is a considerable barrier to the establishment of a new drug. Drugs produced by pharmaceutical companies in Vietnam are generic in nature for which patent protection has expired. The issue of protection of IP rights for pharmaceutical invention is not really paid attention to and does not become a matter of urgency because it is not a 'close' benefit of Vietnamese pharmaceutical companies.

In the near future, following the progress of international economic integration after WTO accession, together with the substantial improvement of the legal system on protection and enforcement of IP rights, the number of applications for pharmaceutical inventions is expected to continue increasing. Recently, in September 2018, on the occasion of the 58th Series of Meetings of the Assemblies of the Member States of WIPO, an agreement on the implementation of WIPO Industrial Property Automation System WIPO (WIPO IPAS) was signed by the Vietnamese delegation, led by the Deputy Minister of Science and Technology, Pham Cong Tac and Francis Gurry, Director General of WIPO.¹⁵ Under this agreement, WIPO will provide free of charge and support the deployment of WIPO IPAS at the National Office of Intellectual Property. This project is expected to start in 2018 and end in 2020.

The WIPO IPAS system is said to have many advantages compared to the existing administration system at the National Office of Intellectual Property; for example, more flexible adaptation, a more user-friendly interface, more suitable for international standards, and easy connectivity with other WIPO tools. The deployment of the WIPO IPAS system at the National Office of Intellectual Property is expected to enhance the speed of processing of industrial property registration applications. It will connect the National Office of Intellectual Property's (NOIP's) application system to WIPO as well as facilitate the sharing of data with other intellectual property agencies and provision of industrial property information to the public.

B. ENFORCEMENT OF THE LAW ON IP RIGHTS FOR PHARMACEUTICAL INVENTIONS

The increase in the number of applications and the number of protection titles issued for the above-mentioned inventions show Vietnamese laws have created a solid basic legal framework to carry out registration for protection of intellectual property. To a certain extent, a basic legal framework has contributed to ensure a proper balance between IP rights and the right to access to pharmaceuticals in order to protect basic rights recognized in the Constitution of Vietnam 2013.¹⁶

¹⁵ National Office of Intellectual Property Vietnam (NOIP) signed a Memorandum of Understanding (MOU) on the implementation of the Industrial Property Management System with WIPO
<[http://www.noip.gov.vn/web/noip/home/vn?proxyUrl=/noip/cms_vn.nsf/\(agntDisplayContent\)?OpenAgent&UNID=8170E9F684965B1B47258316004FFB19](http://www.noip.gov.vn/web/noip/home/vn?proxyUrl=/noip/cms_vn.nsf/(agntDisplayContent)?OpenAgent&UNID=8170E9F684965B1B47258316004FFB19)> accessed 14 August 2018.

¹⁶ Constitution of Vietnam (2013)

'Art 38:

1. Everyone is entitled to health care and protection, is equally entitled to medical services and has the duty to comply with regulations with regard to prophylaxis, medical examination and treatment.
2. Any acts threatening the life or health of other people and the community are strictly prohibited.

...

Article 40:

Everyone has the right to carry out scientific and industrial research, engage in literary and artistic creation and enjoy benefits from those activities.

...

Art 62:

1. Development of science and technology is a primary national policy, playing a key role in the country's socio-economic development.
2. The State shall prioritise investment and encourage investment by organisations and individuals in scientific research, development, transfer and effective

However, there are many negative phenomena in the practice of intellectual property concerning pharmaceuticals. It is possible to separate the actual negative situation of exercising the rights over pharmaceutical inventions into two noticeable points.

First, patent holders of pharmaceutical inventions (which mainly are international pharmaceutical companies) overuse their rights to increase the medicine's price in an unacceptable way, directly affecting the citizens in accessing medicine.

Only one year after Vietnam became a member of WTO and TRIPS, the number of foreign pharmaceutical companies registering to trade medicine increased dramatically from 270 companies (2005) to 370 companies (2007). The number of registered foreign pharmaceutical products increased to 8459 products (2007), accounting for nearly 50% of pharmaceutical products circulating in Vietnam.¹⁷ However, whether the liberalization and opening up of the pharmaceutical market can bring benefit to citizens by creating high quality pharmaceuticals and affordable medicine is an still big concern. Imported medicine, most of which are monopolistic, is closely protected by the TRIPS Agreement (despite the removal of trade barriers and the decrease of the trading cost), but there is still no decline in the price. Conversely, in most cases, prices are constantly rising. There are also dozens of foreign pharmaceutical suppliers that cooperated with Vietnamese distributors to simultaneously request to raise the prices of medicine.

The increase in the number of pharmaceutical companies in Vietnam makes the pharmaceutical market become

more active and competitive, giving consumers more choices. However, there is a risk of uncontrolled medicine quality. According to a 2013 statistic from the Drug Administration of Vietnam regarding the quality of medicine, the number of counterfeit and low-quality medicines entering the market increased. In two years, the proportion of foreign medicine that did not meet quality standards increased more than four times, from 1.34% (2005) to 5.75% (2007), whereas, the number of domestic products not meeting the quality standard is on the downward trend, from 3.0% (2007) to 3.5% (2005). The number of counterfeit medicines also increased from 0.17% in 2007 to 0.09% in 2005, 6 times higher than in 2001 (0.03%).¹⁸

Second, other persons who are not owners and not legally allowed, still use inventions illegally. They do not respect rights of patent holders and commit infringement, directly affecting interests of the inventions' owner. In addition to high-tech goods or other goods for essential consumption, medicines and functional drugs are the most common objects being infringed. IP infringement is tending to increase, and although very complicated, this occurs at every stage of the process of producing and selling products. These acts of infringement negatively affect many entities in different economic sectors.

Around the world, it can be seen that the infringement of pharmaceutical invention is intense and this is one of the products most affected by infringement. Not only in Vietnam, but also in developing countries, in general, counterfeit medicine is the most serious problem, for which the legal framework attempting to prevent or limit the situation has not been completed yet. According to a

application of scientific and technological achievements; shall guarantee the right to conduct scientific and technological research and protect the right to intellectual property.

3. The State shall provide favourable conditions for everyone to participate in and enjoy benefits from scientific and technological activities.'

¹⁷ Drug Administration of Vietnam <<http://www.dav.gov.vn/>> accessed 11 October 2018.

¹⁸ *ibid.*

new report of OECD on counterfeit goods, key factors explaining the existence of counterfeit medicine in developing countries are 'poor medicine control and law enforcement; the distribution channel is not controlled; big price gap between real and counterfeit medicine; lack of effective protection of IP rights; lack of respect for quality assurance; and the corruption of the healthcare system.'¹⁹ The World Health Organization estimates that 6% of the world's pharmaceuticals are fake and 70% of all medicine sold in some countries are fake.²⁰

Between the two above-mentioned phenomena, the first is more popular and directly affects Vietnam, a country with many economic difficulties. The poor people have a high demand for medicine to cure fatal diseases; however, such demand has not been fully met. This situation arises from many issues and it is the responsibility of state agencies, businesses, people and society.

Vietnam has a number of practical measures to assure the enforcement of IP rights, including IP rights in the pharmaceutical industry. As mentioned above, Vietnam has recently developed four measures to assure the enforcement of IP rights: civil measures, administrative measures, criminal measures, and border controls. These measures have a full legal basis for implementation, however in practice, administrative measures seem to be the most commonly used. This can be explained by simple procedures, quick processing, prompt responses to requests of IP rights holders, and ensuring not only precautionary effects but also preventive and deterrent effects by the punishment for infringement.

Associated with each measure to enforce intellectual property rights in pharmaceutical inventions, in Vietnam,

there are many authorities cooperating together to deal with infringements of intellectual property rights:

- (i) The Inspectorate of the Ministry of Science and Technology is a specialized authority responsible for inspecting, detecting and imposing administrative penalties on those who commit acts of infringement of intellectual property rights. The penalties range from warnings and confiscation to destruction of products containing signs of infringement.
- (ii) The market surveillance authority is in charge of regular inspection and supervision of pharmaceutical packaging and manufacturing entities, as well as sale agents of pharmaceuticals; closely coordinating with the Public Security and health authority dealing with entities that commit intellectual property infringements related to pharmaceuticals.
- (iii) The customs authority has the responsibility to control, detect, and deal with acts of infringement of intellectual property rights related to importation and exportation at the border-gate.
- (iv) The public security organs (Public Security Department for Economic Management under the Ministry of Public Security) play an important role in investigating, detecting criminal offenses, prosecuting and imprisoning a number of individuals involving in the production of counterfeit goods including pharmaceuticals.

In the regional sphere, together with some South East Asian countries such as Thailand, China, Laos, and Cambodia, Vietnam has participated in setting up an IP working group in the pharmaceuticals field. This IP enforcement team was established with participation of the pharmaceutical management authorities, public

¹⁹ Jeong -Yeon Lee and Edwin Mansfield, 'Intellectual Property Protection and U.S. Foreign Direct Investment' 78 *The Rev. of Econ and Stats*, 181-186.

²⁰ World Health Organization, 'Substandard and Falsified Medical Products' <[https://www.who.int/news-room/fact-](https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products)

[sheets/detail/substandard-and-falsified-medical-products](https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products)>, accessed 20 October 2018.

security, customs and court authorities, the World Health Organization, United States Pharmacopoeia (USP), and Interpol in the Greater Mekong Sub-region.²¹ This group will strengthen information sharing on counterfeit and low-quality medicines, conduct joint investigation activities, and promote IP law enforcement in the country and among countries in the region. According to USAID (United States Agency for International Development), despite the efforts of many organizations and programs, the manufacturing of counterfeit and poor-quality medicine had a major bad impact on the public health in Southeast Asia. Although the awareness of relevant national and international agencies on counterfeit and low-quality medicines has been improved, the cooperation between organizations and countries is still limited. Therefore, the establishment of a group also aims to build an effective mechanism that encourages and supports the communication, cooperation, and coordination between law enforcement authorities, health agencies, customs, and public security in anti-counterfeit activities in the country, and among countries in the region.

Vietnam has always shown an active role in participating in international institutions and organizations. Currently, the representative of Vietnam is the chairman of the WIPO General Assembly; there are many other prominent aspects to show that Vietnam's position at WIPO and in the international IP arena, is higher. At the opening of the WIPO General Assembly on the morning of 24 September 2018 in Geneva, Switzerland, the Deputy Minister of Science and Technology, Mr. Pham Cong Tac, pledged that Vietnam would be active in

working with other members to develop a fair and comprehensive worldwide intellectual property system. Vietnam has recognized technical assistance from WIPO over the past years and wishes to continue its partnership with WIPO to launch the WIPO IPAS industrial property management system at the National Office of Intellectual Property, and to build an IP National Strategy. These activities of the Vietnam's National Intellectual Property Office show positive signs for the enforcement of intellectual property rights in Vietnam, including the protection of intellectual property rights for pharmaceutical inventions.

5. RECOMMENDATIONS TO IMPROVE VIETNAM'S IP LAW ON THE PROTECTION OF PHARMACEUTICAL INVENTIONS

A number of developing countries have expressed their great concern that implementation of strong IP regimes can 'affect efforts on enhancing public health,' and pharmaceutical patents and treatments 'can hinder governments to work at its best endeavour to address urgent policy issues' with 'reasonable access to health care, which also causes many difficulties for public health programs.'²² High medicine prices create a discrimination between the rich and the poor, in terms of access to medicines. The poor are also the majority in society, especially in middle-income and low-income countries in Europe, Asia, and Latin America.²³ In addition, having to pay large amounts of money for long-term medication can drive patients and their families to poverty.²⁴ Every year, around 150 million people are in financial difficulty,

²¹ Haiquan Online, 'Thành lập nhóm xét tuyển chung: Lợi cho trường và thí sinh' <<http://www.baohaiquan.vn/Pages/Thanh-lap-Nhom-cong-tac-thuc-thi-SHTT-trong-linh-vuc-duoc-pham.aspx>> accessed 12 October 2018.

²² Sarah Rosenbaum, 'The Patient Protection and Affordable Care Act: Implications for Public Health Policy and Practice' (2011) Pub. Health Rep. 130 <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3001814/>> accessed 12 October 2018.

²³ World Health Organization, (WHO) 'Health and Human Rights' <http://www.wpro.who.int/vietnam/topics/human_rights/human_rights_health_factsheet_2013_final_vn_v2.pdf> accessed 15 April 2018.

²⁴ WHO, 'The World Health Report – Health Systems Financing: The Path to Universal Coverage 2010' (Geneva, 2010) 7.

and 100 million people fall into poverty because of the high cost of medical care.²⁵

In light of international treaties on intellectual property, to which Vietnam is a member, Vietnam protects inventions, including inventions in the pharmaceutical industry. However, the current situation of Vietnam, where poverty plagues the majority of people, leads to one difficult question: how to balance interests of patent owners with the interests of the public in ensuring access to medicines? This question will definitely be the most important issue considered. More specifically, the pathway Vietnam wants to follow to improve the policy-making and enforcement of IP laws over pharmaceutical inventions, is maximizing the flexibility of international commitments to reduce the negative effects of the IP regime. In addition, appropriate policies are needed regarding this type of invention to promote the country's economic development, in particular, it is the development of the nascent Vietnamese pharmaceutical industry. With the mentioned pathway from the independent research, the author strongly recommends some specific ideas.

First, it is necessary to specify more clearly, cases where the owner of an invention is not allowed to prevent others from using the invention.

IP Law article 125.2 lists situations where the owner of an invention is not allowed to prevent others from using the invention, thereby permitting the use of the invention 'to serve personal needs or non-commercial purposes or for purposes of evaluation, analysis, research, teaching, testing, trial production or information collection for

carrying out procedures of application for licences for production, importation or circulation of products'. This regulation is built in an enumerated way and cannot cover all practical cases where pharmaceutical inventions are used appropriately. Such regulations can be regarded as an invisible limit that bring many difficulties for Vietnam's laws. If there are any disputes arising out of the right to use pharmaceutical inventions in practice, but the dispute does not fall within cases set out in the regulation, it will be difficult to come to the decision and resolve, even though the use is appropriate and does not cause any significant damage to the rights owner during the term of protection. It is thought that it would be easy to ascertain whether the use of pharmaceutical inventions is an infringement or not if the regulation states three criteria or requirements for the acts of limiting the right of a patent owner, as stipulated in the TRIPS Agreement, which Vietnam is a member of. For example, such acts must be 'limited'; not 'unreasonably conflict with normal exploitation' of the invention; and not 'unreasonably prejudicial to the legitimate interests' of the patent owner as well as the legitimate interests of the third party.

Second, it is necessary to add typical and specific rules for pharmaceutical inventions an object has a major impact on public interests.

Currently, Vietnam has provisions governing the patent review and licensing process. Regarding the pharmaceutical invention, there is a requirement for additions to applications for registration of inventions concerning pharmaceuticals.²⁶

pharmaceuticals in addition to the general documentation required for the invention, the description of the invention must state the results of the clinical trials and pharmacological effects of the drug, at least including the information. : Substance / mixture used; test method (system) used; test results; the correlation between the results of pharmacological effects obtained in the experiment with the practical application of

²⁵World Health Organization, (WHO) 'Health and Human Rights' <http://www.wpro.who.int/vietnam/topics/human_rights/human_rights_health_factsheet_2013_final_vn_v2.pdf> accessed 15 April 2018.

²⁶ Article 100, Article 102 IP Law; Article 6, Article 7, Article 10, Article 11 of Decree 103/2006 / ND-CP; Point 7, Point 10 of Section 1, Section 2 (especially Point 23.10 of Section 2 on additional requirements for SCLQ) of Circular No. 01/2007 / TT-BYT, the application for protection title with the invention of

From the experiences of India, where the number of conditions and requirements for granting protection titles to the pharmaceutical inventions are both increasing; narrowing the scope of protection for pharmaceutical inventions; and giving third parties the right to oppose the grant of a patent within a specified period of time.²⁷ This requirement further enhances the technical level of the domestic pharmaceutical industry in order to create truly innovative and creative pharmaceutical products compared to previous inventions.

During the period from 1970 to 2005, the Indian Patent Act protected inventions as a process and also protected companies making long-term investments in research and development medicine in India.²⁸ Additionally, the Indian Patent Act of 1970 allowed Indian companies, if they qualify for the manufacture of a pharmaceutical formula, to be licensed by the company that owns the patent to produce under a voluntary license. Article 84 of this Act also permitted a compulsory license, which obliges the company that owns the patent to issue a license to another company manufacturing that drug if (1) the patent owner cannot satisfy the demand for the medicine and access to the medicine; (2) drug prices are too high compared to the affordability of the public; (3) the company is implementing a patented product on Indian territory. Since 1978, India has emerged as the leading center for the production of generic medicine.

Third, the government could consider a plan to build a knowledge database on traditional medicine in Vietnam. Among traditional knowledge, traditional medicine is an

pharmaceuticals in prevention, diagnosis and treatment of diseases.

²⁷ Patent Act of India s 84, '(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:- (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a

important part of human healthcare. It is a combination of knowledge, skill and practice, based on theories, creeds, and indigenous experiences from different cultures, used to promote good health, and to cure disease.

According to statistics of the World Health Organization for Vietnam in 2003, there were 39,381 traditional medicines recognized from 54 ethnic groups. The exportation of traditional medicine reached about 10,000 tons, contributing to export turnover of USD 1-2 million. Commercial value of traditional knowledge is actually much higher than that. In particular, about 80% of the world's population uses traditional medicine for health care.²⁹ It is clear that traditional medicine is a field in which Vietnam has many advantages, from a rich flora and fauna with high quantity and quality, especially medicinal plants, to indigenous knowledge about traditional medicine. This is a strength that Vietnam needs to protect.

The construction of a traditional knowledge database on traditional medicine in Vietnam has particularly important benefits such as:

- (i) Providing a basis for all organizations and individuals to exploit human health protection without having to apply for patents. Because the traditional knowledge of medicine belongs to all people, this database will ensure the right of people to receive medicine and healthcare;
- (ii) A database of patents, so that the reinventing of existing inventions does not happen. This can help avoid the invention losing its novelty, as well as the

reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.' <<http://www.wipo.int/edocs/lexdocs/laws/en/in/in065en.pdf>>.

²⁸ The Indian Patents Act of 1970.

²⁹ Luu Thi Thanh Nga, 'Building and Exploiting a Database on Traditional Medicine to Ensure the Right to Traditional Knowledge in Vietnam' (Master's Thesis, Hanoi National University, 2015).

case that traditional knowledge of Vietnam is used by foreign enterprises and applied for a patent; and

(iii) An effective solution to avoid the loss of traditional knowledge by transferring knowledge about traditional medicine to the people in Vietnam. Accordingly, under the form of electronic digitization, the use, searching, and preservation of ancient knowledge becomes more convenient.

Fourth, the scope of protection should be extended to the new subjects as an effective solution for the research and development of the pharmaceutical industry in a developing country like Vietnam.

Research and development of new medicines costs a lot of time and money, especially in a developing country like Vietnam, where it is difficult to invest in new research and development. Previously, when the IP Law had not yet entered into force (besides protected products and processes), a group of subjects was also protected under patent as is the group (known for active ingredients) used for new purposes. According to the current IP Law of Vietnam, this group is no longer protected. However, it is important to re-establish the patent regime for this group. It can be seen throughout the history of the pharmaceutical industry that many of substances have been found to have new effects, in addition to originally licensed prescriptions. Many active ingredients may be used in new formulations to improve the effectiveness of medicines, such as chewable tablets, oral solution, or transfer from injectable to non-injectable forms; long-acting tablets to reduce the number of daily doses, and to reduce side effects caused by medicine absorption through the digestive tract. Review of medicines circulated is a less risky strategy, which reduces the cost of clinical trials and quickly brings products to the market. Once the pharmacological information and safety of the medicines has been confirmed, clinical trials are implemented in a faster way. Simultaneously, production

processes also becomes simpler and do not require too much financial investment and effort, especially in a developing country like Vietnam, where research funding is still heavily dependent on limited state budgets. This seems to be a more suitable pathway than the research and development of new medicines. Some countries also have a policy of encouraging this kind of research that reviews known medicines. Under the Hatch-Waxman Act in the United States, the government promotes this kind of research by extending the term of protection by up to three years for new indications of licensed drugs.³⁰

In addition to the recommendations to complete specific provisions directly related to pharmaceutical inventions, it is necessary to take synchronous measures:

- (i) To enhance the capacity and performance of competent authorities in the enforcement of intellectual property rights over pharmaceutical patents.
- (ii) To develop the domestic pharmaceutical industry; enhance the manufacturing capacity and the research and development of pharmaceuticals in domestic enterprise while raising the enterprises' awareness on the intellectual property law in general; and the protection of inventions related to pharmaceuticals in particular.
- (iii) To invest in the training of human resources with profound expertise in the field of pharmaceuticals in the relevant authorities involved in the granting of patents to the pharmaceutical invention, as well as the IP rights enforcement authorities for the protection of pharmaceutical invention.
- (iv) To establish the international cooperation in the field of pharmaceuticals

According to Report No. 241 / BC-SHTT of the NOIP, dated 19 January 2017, reviewing the upcoming year's work performance and the direction and tasks of the NOIP in

manufacture of generic drugs by the pharmaceutical industry and established the modern system of government generic drug regulation in the United States.

³⁰ The Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), informally known as the Hatch-Waxman Act, is a 1984 United States federal law which encourages the

2018, a proposed task is to continue to build and complete the legal system on IP rights, as well as the state management of IP rights, in order to meet the requirements of Vietnam's socio-economic development during this period of increasing integration into the global economy. This includes outstanding activities related to the protection of pharmaceutical inventions; it is the development of a draft circular, guiding the transfer of the right to use the invention under compulsory licenses in the pharmaceutical industry. This is good news for Vietnamese pharmaceutical companies to produce medicines during the protection period, and for the majority of poor people in Vietnam to access latest scientific advances in the world to face diseases.

6. CONCLUSION

Considering the specific characteristics of pharmaceutical inventions and their importance to public health, as indicated in this article, prevailing provisions in Vietnamese IP law are not sufficient. As an important treaty on intellectual property, in the new world's economy, TRIPS demonstrates its role in setting out the rules to harmonize countries' IP regimes. However, each country is at different stages of development. TRIPS has left developing countries a great deal of flexibility by allowing those who have a great impact on public interest take advantage of the patent system. This article gives the author's personal opinion on how to develop and orientate in order to improve IP provisions for pharmaceutical inventions. The paper also asserts that new legislation and related policies should be carried out in concert. The goal of achieving a healthy balance between the interests of patent owners and benefit to people in accessing pharmaceuticals should be a high-priority task in a developing country like Vietnam.

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