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THE IMPACT OF INTELLECTUAL PROPERTY CHAPTER UNDER THE COMPREHENSIVE AND PROGRESSIVE AGREEMENT FOR TRANS-PACIFIC PARTNERSHIP ON VIETNAM PHARMACEUTICAL MARKET

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Abstract

The Intellectual Property Chapter under the Comprehensive and Progressive Agreement for Trans-Pacific Partnership has introduced new obligations for Vietnam, notably the protection of Undisclosed Tests or Other Data. This study is of utmost importance as it aims to thoroughly examine the implications of these new obligations, focusing on identifying the benefits for intellectual property rights holders and the public's access to new medicines.

Keywords Intellectual Property law, CPTPP, Undisclosed Test or Other Data, public health, pharmaceutical market, Vietnam.

INTRODUCTION

The CPTPP Agreement officially took effect on December 30, 2018, for the first six countries to complete the ratifying procedures, including Mexico, Japan, Singapore, Canada, Australia, and New Zealand. For Vietnam, the CPTPP Agreement officially took effect on January 14, 2019 .

CPTPP covers essential areas such as trade in goods and services and issues related to state-owned enterprises, competition law and policy, environmental cooperation, labor, dispute resolution, and intellectual property. Regarding other Free Trade Agreements, the CPTPP has many differences, including strict requirements and commitments. First, the CPTPP provides a comprehensive market approach through tariff reduction and removing non-tariff barriers for all goods, services, and investments, creating favorable conditions for businesses and society. Second, the regional approach to making commitments facilitates the development of production and supply chains, promoting trade continuity, strengthening regional cooperation, and cross-border integration. Third, the Agreement has solved the problems the digital economy faces because of the enormous role of state-owned enterprises. Fourth, trade is inclusive, the CPTPP includes new elements to

ensure that economies of all levels of development and businesses of all sizes can benefit from trade. The Agreement also includes specific commitments to developing and enhancing trade capacity to ensure that all Parties can meet their obligations in the Agreement and take full advantage of its benefits. Finally, the CPTPP is the foundation for regional integration - the premise of Asia-Pacific integration.

The Intellectual Property Chapter under the CPTPP Agreement

TPP or CPTPP negotiations are based on all members' equal status. However, the options proposed in each chapter of the TPP always show the imprint and impact of some proposed members. Chapter 18 of TPP on intellectual property (led and pursued by the United States during the negotiation process) has recognized the policy of deep and wide protection of intellectual property objects compared to TRIPS and other free trade agreements intertwining among the members of TPP. The achievements of the United States in Chapter 18 shall increase exports of goods and public value for United States labor. The protection aims to provide standards and high enforcement of intellectual property rights throughout the region. This also invisibly represents the creative and technological advantage of the United States. The standards of protection do not affect or change the laws of the United States, but they considerably affect other members, especially developing members like Vietnam.

Overall, the TPP defines a policy to protect intellectual property rights to (i) Promote great protectionism and a balance between protectionism and rights enforcement; (ii) Promote products containing intellectual property rights; (iii) Focus on common infringements such as counterfeit goods, appropriation of business secrets; (iv) Promoting a clear, transparent and efficient system of filing and registering patents and trademarks; (v) Promoting the development and access of new and conventional drugs; (vi) Developing and creating institutions for digital technology, including creative content; (vii) Prevent the expansion of geographical indication protection, take measures to protect the rights of pre-existing trademark owners, and regulate the everyday use of the concept. The existing members of CPTPP have agreed to suspend some commitments under the IP chapter, allowing members more time to prepare. The CPTPP Agreement indeed shall have many advantages for economic growth. It not only improves legal protections for firms and individuals doing business but also protects the welfare of customers. However, there will be several problems once the IP chapter is enforced.

Subjects of new invention protection under the commitments of the CPTPP Agreement

Chapter 18 of the CPTPP Agreement establishes a new protection regime, which is assessed to be much higher than the current level of protection recognized in The Agreement on Trade-Related Aspects of Intellectual Property Rights (Herein referred to as “TRIPS” or “TRIPS Agreement”) as well as the Intellectual Property Law of Vietnam. Unambiguously, Chapter 18 of the CPTPP Agreement recognizes the general agreements of countries in the field of patent protection, including provisions on the scope of objects to be protected, adjusting the term of patents, and protection of test data. In this chapter, the provision that expands the scope of the subject of patent protection is considered to have a substantial impact on Vietnam's patent protection system. Article 18.37.2 of the IP chapter has stated that:

“Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at

least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such."

Regarding the provisions of Vietnam IP law, an invention is a technical solution in the form of a product or process intended to solve a problem by applying natural laws . To be protected as an invention, a product or process must meet the requirements of novelty, inventiveness, and industrial applicability . Accordingly, new uses of a known product, new ways of using a known product, or new processes cannot be protected as inventions. This is because they independently do not have enough novelty or sufficient level of creativity . These new regulations will create a significant impact on Vietnam's pharmaceutical market.

Impact of the IP chapter under the CPTPP Agreement on the Vietnam pharmaceutical market

Currently, the Vietnamese government is dealing with balancing interests among rights holders. Test data protection or other confidential data protection is essential to agrochemical or pharmaceutical manufacturers because obtaining such data or other confidential data requires high investment costs, time, human resources, equipment, machinery, etc. Therefore, the exclusive use of tests or other confidential data will help manufacturers recover their investments and bring them benefits and profits. This will prevent the following manufacturers from being able to apply for marketing authorization without having to re-test.

However, such demand for manufacturers poses an extreme issue, especially for developing countries like Vietnam. Exclusive use of experimental or other confidential data for pharmaceuticals can seriously affect people's access to medicines. After successful research and marketing authorization, a patented brand-name medicine will be called a medicine. With this patent, the owner will have the exclusive right to manufacture the original brand-name medicine, and this explains why pharmaceutical companies will often pay a very high fee to be allowed to use the invention. In Vietnam, pharmaceutical companies that want to produce a brand-name medicine frequently have to wait until the patent protection granted to a brand-name medicine expires to proceed with production according to that brand's formula. The reason is that the scientific level and financial potential are limited. This manufacturing process is called generic medicine manufacturing. This medicine is bioequivalent to a brand-name medicine, contains the same amount of active ingredient, is used under the same conditions of bioavailability, and has the same rate of absorption into the body as the brand-name medicine . The same applies to medicines of biological origin. With a long term of protection plus the possibility to extend the protection period through the application of a new designation, new formulations, or even new routes of administration, it may seriously affect the Vietnam pharmaceutical industry. Thus, it will be problematic for the public to access new medicines due to high costs with limited supply.

Limited access to medicines will reduce the ability to protect public health and control epidemics. The COVID-19 pandemic has clearly shown this problem; with a restricted medical foundation, developing a vaccine against the Coronavirus nCoV for Vietnam may be much slower than in other developed countries . The inability to access experimental or other confidential data for vaccines against the nCoV virus will make the pandemic more challenging to control and dangerous when Vietnam (as well as other poor or developing countries) cannot take the initiative in production . In addition, the imbalance in the

distribution of vaccines (even though vaccines are distributed through the Covax mechanism) exacerbated the epidemic. Regarding finding solutions, Vietnam stipulates that when applying for marketing authorization for test data or other confidential data, the competent authority must ensure that all necessary measures are taken to keep such data confidential, that it is not used for unfair commercial purposes, and that it is not disclosed. The exception can only be applied once the aim of disclosure with test data or other confidential data is to protect the public. Hence, it is necessary to develop more specific solutions to ensure the law is completed under the commitments of the CPTPP Agreement on protecting confidential data or other data.

SOLUTIONS

In the 2001 Doha Declaration , all WTO members, including CPTPP members , recognized the importance, necessity, and ethical relevance of the flexible application of TRIPS provisions to protect public health. The abuse of pharmaceutical patents has reached a lot of opposition from the first round of negotiations of the TPP Agreement and later the CPTPP when it directly affects the public's right to access medicines, particularly in poor or developing countries. Therefore, based on the flexible application of the arbitrary provisions of the TRIPS Agreement, the spirit of the Doha Declaration based on being consistent with the commitments in the CPTPP, Vietnam must apply several measures to protect public health and prevent the abuse of pharmaceutical patents. Regulations on compulsory licensing of patents in the pharmaceutical sector should be applied flexibly. Because of that, Vietnam can flexibly apply Article 18.40 of the CPTPP to allow the transfer of patent use rights in the pharmaceutical sector. Currently, the Law on Intellectual Property of Vietnam has also specified the bases for compulsory patent transfer, such as applying inventions for public purposes, ensuring to meet the urgent needs of the public; the patent owner does not fulfill the obligation to use the invention or engages in anti-competitive behavior;... However, the competent authorities do not always have sufficient grounds to compel the licensing of an invention. In addition, the licensee's right to use pharmaceutical inventions when performing production is also very limited in terms of production scale and scope of use.

Establishing a mechanism for the parallel import of medicines would be a solution, as the importation of medicinal products is legally marketed abroad. In Vietnam, foreign medicines, especially those manufactured under the decision on compulsory licensing of patents, usually have lower prices than medicines manufactured under the license of the patent owner, although taxes on imports are included. This mechanism has been facilitated through Intellectual Property Law; however, the circulation licensing, applicable tax rates, drug price adjustment mechanism, etc., still have many shortcomings that discourage many organizations and businesses from investing in this parallel import policy. Then, there is a need to create favorable conditions through legal corridors to provide maximum support for companies to carry out the parallel import of pharmaceuticals.

The abuse of intellectual property rights should be considered an anti-competitive act, especially in the case of exclusive use of inventions. The exclusive use of an invention brings economic benefits to the right holder and many associated privileges. However, to balance the interests of the subjects, the law on intellectual property still gives the rights holder exclusive rights for a certain period. That term is acceptable when carefully researched based on balancing the interests of the parties and ensuring fair competition in the market between owners.

Therefore, acts of willful or attempting to delay the end of a fixed monopoly period should be considered an abuse of intellectual property rights and a substantial limitation of competition.

CONCLUSION

In summary, Vietnam's competition law should consider supplementing and amending specific provisions on the abuse of intellectual property rights, and it should consider it an anti-competitive act.

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