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COMPULSORY LICENSING OF PATENTED PHARMACEUTICAL INVENTIONS

ПРИМУСОВЕ ЛІЦЕНЗУВАННЯ ЗАПАТЕНТОВАНИХ ФАРМАЦЕВТИЧНИХ ВИНАХОДІВ

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The products of the pharmaceutical industry are of strategic importance for the health of all mankind, which is especially felt in the face of global epidemiological threats. Legal regulation in this area is aimed at ensuring the public interest and is controlled at the national and international levels by various legal means, including through the introduction of compulsory licensing of pharmaceutical inventions. The range of issues that need to be addressed in the implementation of such a mechanism is most often governed by local legal rules to balance the interests of the public health care, the interests of investors and the patentee concerned since only at the national level can state objectively investigate the situation in the pharmaceutical field.

The author analyzed three local cases that have taken place in recent years in India, Egypt, and Germany, where countries have reflected different approaches to compulsory licensing for the manufacture and sale of drugs. Besides, some states have experienced consequences such as a drop in the volume of foreign investment within the pharmaceutical sector, which have been associated with a decrease in the patentee's exclusive rights protection. Three intergovernmental cases examined by the WTO Dispute Settlement Body in recent years with the participation of the United States, Argentina, Brazil, India, and the Netherlands were also analyzed.

Despite arguments against compulsory licensing, it is hard to underestimate the appropriate protection mechanisms introduced by the Agreement on Trade-Related Aspects of Intellectual Property Rights for the rights it establishes. By establishing the possibility of giving other companies the right to produce generic drugs at a more affordable price, thereby increasing the number of medicines, the WTO law considers the country to provide its citizens with access to the medical field and is concerned about less secure sections of the population. It is important, however, that appropriate decisions should be taken in the light of the common need and without possible abuse of this right by the relevant authorities and companies that are issued compulsory licenses.

Key words: compulsory licensing, public health, TRIPS, WTO, non-voluntary licensing, intellectual property

Продукція фармацевтичної промисловості має стратегічне значення для охорони здоров'я всього людства, що особливо відчувається під час епідеміологічних загроз глобального характеру. Правове регулювання в цій сфері спрямоване на забезпечення публічних інтересів і контролюється на національному та міжнародному рівнях різними правовими засобами, зокрема і шляхом запровадження примусового ліцензування фармацевтичних винаходів. Обсяг питань, які повинні бути встановлені у процесі застосування такого механізму, найчастіше регулюється локальними правовими нормами для збалансованого захисту інтересів публічної охорони здоров'я, інтересів інвесторів і відповідної компанії, яка є патентовласником, адже тільки на національному рівні держави можуть об'єктивно дослідити ситуацію у фармацевтичній сфері.

Авторка статті проаналізувала три локальні справи, які сталися впродовж останніх років в Індії, Єгипті та Німеччині, де країни застосували різні підходи до надання примусової ліцензії на виробництво та продаж ліків. Крім того, деякі держави зіткнулися з такими наслідками, як зменшення обсягу іноземних інвестиційних вкладів у межах фармацевтичного сектора, що було пов'язано зі зменшенням рівня захищеності ексклюзивних прав патентовласника. Також були досліджені три справи міждержавного характеру, розглянуті органом врегулювання суперечок Світової організації торгівлі в останні роки за участі Сполучених Штатів Америки, Аргентини, Бразилії, Індії та Нідерландів.

Незважаючи на аргументи проти примусового ліцензування, не треба недооцінювати відповідні механізми захисту, запроваджені Угодою про торговельні аспекти прав інтелектуальної власності щодо встановленого нею права. Встановлюючи можливість надання іншим компаніям права випускати дженерики за доступнішою ціною, тим самим збільшуючи кількість лікарських засобів, у праві Світової організації торгівлі країна розглядається як така, що надає доступ своїм громадянам до медичної сфери, турбується про менш захищені прошарки населення. Важливо, однак, щоб відповідні рішення ухвалювалися з урахуванням загальної потреби та без можливих зловживань цим правом із боку відповідних органів і компаній, яким видаються примусові ліцензії.

Ключові слова: примусове ліцензування, охорона здоров'я, ТРІПС, СОТ, недобровільне ліцензування, інтелектуальна власність.

The relevance of topic. Innovations play a pivotal role in our society, which means, that they create a new way of our living. It is not rocket science that the medical field has always been in dire need and still needs new drugs, devices, despite any breakthroughs. This is caused by new types of diseases, mutations of viruses and bacteria. Nothing remains the same. It is crucial, therefore, to give access to new treatment which can be considered of high importance and can sustain public health as HIV/AIDS curing drugs, which show a vivid example. However, it is necessary to sustain a balance and not forget about manufacturers who produced such a drug or way of healing. Hence, for this purpose the Article 31 of Agreement on trade-related aspects of intellectual property rights (hereinafter – TRIPS) was created, where the first point of the other use without authorization of the holder of a right has established the necessity to determine in each case separately, i.e. "shall be considered on its individual merits" [1].

The purpose of the article. Accessibility is a tenseness of the world today, sometimes patients from both developed and developing countries cannot purchase the expensive patented medicine, even if they are in urgent need. This is one of the main reasons for providing compulsory licensing. However, it is extremely difficult to find the real necessity for such licensing in some cases, where the different aims are more vivid than just public health.

Results of analysis of scientific publications. The number of scientists examined the issue regarding compulsory licensing, putting more attention to particular cases of specific of applying of TRIPS in national legislation. For example, Raadhika Gupta, Carlos M. Correa, Charu Mathur, Manzoor Elahi, Marina Zavyalova, Abeer Allam, Patricia Cappuyns, Jozefien Vanherpe, Tobias Wuttke, Vitalyi Pashkov, and others. Dr. Kyung-Bok Son did great research concerning the aspects of the necessity of filing the compulsory licensing, providing charts and diagrams for the clarification of some aspects.

The main body. TRIPS in Article 31 does not expressly refer to the phrase "compulsory licensing", however, this provision is known as one that deals with this issue. TRIPS itself has a reference what "the other use" means, determining it as any other use than that allowed under Article 30. The latter is a broad provision that gives permission to the member states to provide limited exceptions to patent rights [1]. As an interesting remark, when TRIPS was originally negotiated, Article 30 was perceived as a mechanism similar to "fair use" in the field of copyright [2].

It is necessary to read Article 31 not alone, but taking into account Article 2 (1) of TRIPS and Article 5 (A) (2) of the Paris Convention, and the permission of compulsory licensing, therefore, is implied [3]. The latter Convention stipulated the necessity for each state to stipulate in the legislative acts the measures for granting compulsory licensing. This instrument should prevent the abuses which can result from the exercise of the exclusive rights conferred by the patent [4].

The concerns of developing countries about the possible impact of patents in the pharmaceutical sector led the World Trade Organization (hereinafter – WTO) to adopt, in November 200I, the Doha Declaration on the TRIPS Agreement and Public Health'. The Declaration reaffirmed, inter alia, that the granting of these licenses (and government use) was one of the clearly admitted flexibilities under the TRIPS Agreement', and that WTO Members were free to determine the reasons for the granting of such licenses [5].

Dr. Kyung – Bok Son in his research chose a set of explanatory variables, specifically geographical, economic, and political preconditions of a state to provide such a measure. As for the last one, the author stipulated that the political system as a matter might induce the increased supply of public goods and public policy, or politicians might attempt compulsory licensing to legitimize their political party or regime [6]. As for this variable, the possible abuse of the right to file a compulsory license can appear.

Given the history, it would be reasonable to assume that compulsory licensing has been mostly attempted in Africa, Asia, and Latin America. However, analyzing legislative acts of the 18th century, surprisingly, high-income countries introduced compulsory licensing to complement the intellectual property system and develop their own industrial policy. Firstly, countries commenced just with copyright issues, not patents, but the general ideas can be compared. In the USA by the Copyright Act of 1783 was established that copyrighted books should be sold at a reasonable price in sufficient quantities; otherwise, it would be possible to file a complaint with the court, similar to the situation of the Statute of Anne [6]. The idea of sufficient amount and reasonable value permeates the idea of compulsory licensing if it is taken for granted that such an instrument of patented pharmaceutical inventions is used for public health purposes now.

But the real problem arose when such public health aim should be determined as a reason for the lawful violation of the exclusive rights of the patent holder. To be more precise, it is the right over the utilization of the invention for a certain period of time, when the protection is in force. What is decisive in the compulsory licensing, therefore, is that the protection of the public interest should be much higher than business interests.

Almost all countries have rules concerning compulsory licenses in their patent legislation. Whilst these national provisions are not identical, they must all comply with the twelve conditions for the licensing on the mandatory grounds schemes set forth in Article 31 of the TRIPs Agreement. One of the necessary requirements, prior to the grant of a compulsory license, the proposed user must have made reasonable efforts to obtain a license from the patentee, so the company should attempt to conclude a voluntary licensed agreement with the patentee. An additional condition stipulated in TRIPS is that the compulsory license must predominantly regard supply of the domestic market of the state granting such a license. This requirement does not apply in case, when a compulsory license is granted to fix an anticompetitive practice. In that case, the abovementioned requirements regarding prior negotiation and/or notification mentioned also do not apply [7].

Taking a case Bayer v. Natco (2012) as a vivid example in the practice of the developing country. It was the first Indian case regarding the compulsory licensing of pharmaceutical products. M/S Bayer Corporation (or Bayer) invented a medicine called "SORAFENIB" which is needed in the treatment of liver and kidney cancer and then sold with the name "NEXAVAR". The overall cost during the 1994–1999 research period was $275 million that included not only Bayer expenditures but also Onyx Pharmaceuticals, who invested in this drug under the collaboration agreement. Only in 2006 the medicine first entered the market at all, in India, however, it began to be launched in 2008. By 2008, sales of Nexavar were reported at $678 million, for a total of $1,2 billion within three years. Natco Pharmaceutical ltd (or Natco Ltd), an Indian generic pharmaceutical company, filed an application for voluntary license to produce such medicine in 2010 but received a rejection from Bayer Company. As a result, the generic company asked the Controller of Patents for getting a compulsory license and quite succeeded in this, but with some limitations. Natco Pharmaceutical ltd could produce the drug, but it was prohibited to give a sublicense for other companies. As Bayer found, such medicine obviously an amazing treatment for liver and kidney cancer, but the possibility existed, that it could heal other diseases. The Controller of Patents limited Natco Ltd's sales just for purposes that had already existed notwithstanding the next possible proliferation of this product to cure another type of cancer. Compensation for such use was 6% (royalties), but then the appeal court increased it to 7%. Additionally, the price of the Sofaranib should not exceed Rs. 8 880 for a pack of 120 tablets [8]. The overall arguments for the application the compulsory licensing mechanism were the following:

1. The drug was not in sufficient amount in the market and not for a reasonable price. Section 84 (1) (a) of the Indian Patent Act stipulated that the "reasonable requirements of the public with respect to the patented invention" must not have been satisfied, and it has occurred in this case.

2. The work out of the drug in India was not followed. Section 84 (1) (c) of the Indian Patent Act established, that compulsory licensing should be worked in India, but the question arose during the proceeding what does this phrase mean. Natco Pharmaceutical ltd insisted that it means "manufacturing" and due to ownership of specific techniques, Bayer was able to manufacture this medicine inside the borders. However, the patentee argued that it had permission to import since 2008. But whatever the phrase means. Patentee failure, because in 2008 it did not import the medicine at all and in 2009–2010 it was done in too low number [9].

After that case, the level of foreign investments in the pharmaceutical field diminished by 65,2% (from $3,2 billion to $1,1 billion) and it was connected with the weakening of principles regulated exclusive rights in the patent sphere [10].

The important points of the case touched the necessity to make medicine available for different groups of the society given the fact that the average person needed to spend more than 4-years-salary to receive the treatment with this drug.

In the above-mentioned case, it is hard to argue with the decision of the Controller of Patents. Natco ltd had already asked about voluntary licensing agreements and received a rejection. The opportunities of Indian society were not so high, but the necessity was. Therefore, the instrument provided by Article 31 of TRIPS was utilized according to the overall understanding of public interest and public health.

However, it is hard to express a similar opinion regarding the next case, which happened in 2002 in Egypt. Pfizer-Egypt, the Egyptian subsidiary of Pfizer Inc., succeeded in its four-year maze to obtain permission from the government to manufacture and sell its popular impotence drug, Viagra, in Egypt. However, the price was high and local companies commenced claiming and as a result after only 2 months being in the market, government licensing all companies who had applied on mandatory grounds. Hence, not only Pfizer-Egypt was able to sell that drug, but 12 enterprises more. The problem is that the government's aim was thinking about

local companies and poor people, not foreign ones. "We will for certain grant market authorization for all Egyptian companies that applied to produce Viagra", said the president of the Ministry of Health department, Dr. Mostafa Ibrahim. From long term economic purposes it can be understood, however, due to the loss of the profit by Pfizer company (Viagra produced by this company after the compulsory licensing plummeted down by 19% and was sold by 1/20 from the first price) all investments inside the country regarding medical and, especially, pharmaceutical sector reduced by leaps and bounds and steady growth from the 1990s stopped in 2002. For instance, the USA investments dropped from $1,6 billion to $390 million in the fiscal year [11].

Comparing these cases both of which occurred in developing countries it is definitely hard to found out the same public interest. In India, the Controller of Patents expressly listed a set of arguments about prices, accessibility, etc. Concerning the Egyptian ones such arguments even would not be objective due to the absence of the normal time duration when citizens had an opportunity to purchase the product. Moreover, in Indian company that received a license on mandatory grounds had attempted to conclude a voluntary licensing agreement, but had not succeeded in that option. At the same time, nothing was said about such an agreement in the Egyptian case.

But the instrument of the compulsory license is also utilized in already developed states. One of the pivotal cases happened in Germany. The main reason to mention the judgment of 11 July 2017, i.e. the Raltegravir Judgment of the Bundesgerichtshof (BGH or Federal Court of Justice) (hereinafter – the Raltegravir judgment) in this work is the point, that the license was received in order to continue the selling of the drug by the company which previously could be found as a violator of the exclusive rights of the patentee.

The Japanese company Shionogi had claimed infringement proceedings before the Regional Court of Düsseldorf (Landgericht or "LG") against Merck, requesting injunction relief in the summer of 2015. Merck, in its turn, filed a request with the Federal Patent Court (Bundespatentgericht, or "BPG") to grant a compulsory license by way of a preliminary injunction and in 2017 received it [11]. The infringement proceedings were however stayed by the District Court until the final decision of the EPO's Boards of Appeal in 2017 [12]. Thus, BGH not just agreed with the decision regarding compulsory licensing, but also argued its position with the respect of § 24 of the German Patent Act. Firstly, the applicant must try without success for a "reasonable period of time" to obtain a license under "reasonable conditions". The Federal Supreme Court also made clear that mere fake negotiations are not acceptable. Despite the applicant's acting without the necessary confidence, a compulsory license is governed on an urgent basis. Secondly, the necessity to decide whether the public interest in the case exists. Although the German Patent Act has not the definition of the term, the BGH established that due to the specific of the patentee's exclusive rights, public interest commenced to take on specific features as really a small group of destitute people. Given the fact that some individuals with HIV/AIDS cannot be treated with another drug but with the same effect. With respect to this group and the health of other people, the BGH found it reasonable to licensing the company on mandatory grounds [11]. It is important to note that the dispute concerned the issuance of such a license to continue the sale of a drug that has already established itself on the market as an effective one. In this case, the question of creating a new production or the need to reduce drug prices was not addressed. And as in the previous case in India, the court limited the opportunity of trading the drug to the territory of Germany [9].

If to compare these three cases which occurred in the frames of national legislation, the different approaches were used. Whilst Indian and German judgments pursued the aim of public health and care for their citizens, it is not clear what exactly the Egyptian authorities pursued.

The significant point arises also with Article 8.1 of TRIPS, which refers to public health and nutrition. Compulsory licensing requires public intervention based on well-founded, clearly explained public goals. According to this, a mere designation of public health is insufficient for compulsory licensing to be in conformity with TRIPS. As for the Egyptian situation, therefore, RA Castellano stipulated that that case showed a lucrative political operations [13].

The disputes regarding the compulsory licensing appeared not only in the frames of national systems between companies, but also sometimes affect national interests. These cases, therefore, are heard in the WTO institutions. For instance, the case DS196: Argentina — Certain Measures on the Protection of Patents and Test Data [14], where the USA was a complaint and Argentina acted as a respondent. United States of America cited nine different articles of TRIPS, including 31 one. Consultations were requested in 2000 and in 2002 the dispute ended by the notification about a mutually agreed solution. The complaint claimed about the inconsistency of Argentina's legislation with TRIPS, precisely, the gist of the US complaint was that Argentina failed to provide in its legislation certain aspects regarding intellectual property rights. Claims concerning compulsory licensing dealt with certain safeguards on an invention granted on the basis of inadequate working by the patent holder. Adequate measures to prevent infringements of patent rights were claimed as well. The mutually agreed solution includes statements that countries analyzed the law of Argentina and solved issues without prejudice to the rights and obligations of Argentina and the United States under the WTO agreements [14].

The problem arose when hearings in WTO proceed too long as in the cases DS408 and DS409 (European Union and a Member State – Seizure of Generic Drugs in Transit), where India and Brazil act as applicants respectively [15; 16]. Both applications were filed in the first middle of May 2010, and still remain in the same position: in consultation, which means that complaint requested consultations with the respondent, however, neither dispute panel established nor withdrawal or mutually agreed solution notified. India and Brazil claimed about the reiterated seizures on patent infringement grounds of generic drugs originating in India but transiting through ports and airports in the Netherlands to third-country destinations and referred not only to article 31 of TRIPS but the GATT as well.

Notwithstanding benefits that the country and society can achieve as the availability of needed goods and services for all the parts of the citizens or diminishing the level of unemployment due to the hiring employees on the jobs providing by enterprises that received these kinds of licenses, there are some drawbacks as well. Reclining political issues with possible neo-colonization caused by the dependence of highly advanced technology in developed states, the investments can be also reduced. Generics may not be produced with the same quality standards due to the lack of the scholars` experience. But one of the most significant points is that manufacturers rely on investments to continue its researches, but whilst cash flow stopped, the laboratories would not be able to create new treatments. Putting all the pros and cons together, the pivotal aim of human health would prevail all over the disadvantages for the business activity [17].

Conclusion. Like all cases developments, the mechanism of compulsory licensing is perceived as a double-edged sword. National legal acts of the state members to TRIPS provided the way of receiving the right to produce or sell generics and, therefore, maintain public health. In the case of possible insufficient regulation, other countries have the right to request for consultations in the WTO to improve the loopholes. However, this instrument of licensing can affect the state economy with negative consequences due to the nature described as interference into business activity.

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