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TEMPORARY RESTRICTION OF PATENT RIGHTS IN THE CONTEXT OF COMPULSORY LICENSING OF MEDICINAL PRODUCTS: NATIONAL AND FOREIGN EXPERIENCE

Abstract. *The purpose* of the article is to study the mechanism of temporary restriction of property patent rights to medicines, which is called “compulsory licensing”, based on the analysis of the relevant national and foreign experience. **Research methods.** To achieve the study’s goal, the author has used general scientific and special methods of cognition; the comparative law method, which has allowed comparing the domestic and international experience of legal regulation of compulsory licensing of medicines, plays an important role in the research process. **Results.** The legal categories denoting the procedure for compulsory licensing of medicines in the world practice are examined. The international legal formation of the institution of restriction of patent rights by issuing compulsory licenses in general, incl. medicines, is covered. The research has analyzed the experience of introducing the legal institution of compulsory licensing of medicines in individual countries (the case of the USA, Germany, Great Britain, France, and China). The author has separately elucidated the fact that compulsory licensing of medicines received a new impetus to development in the context of the world’s fight against the COVID-19 pandemic. The cases of many countries which adopted specific legal regulation in the area concerned have been analyzed (Australia, Brazil, Canada, Chile, Colombia, Ecuador, Hungary, Indonesia, and Russia). **Conclusions.** As a result of the study of the experience of the above countries, the author concludes that compulsory licensing of medicines is used primarily to protect the national interests of the state, in particular economic ones, as well as to ensure the protection of public health. Based on the analysis of the current legislation of Ukraine, the author asserts that the institution of compulsory licensing of medicines is at the stage of initial development: today there is no proper legal regulation of this group of legal relations, which makes its functioning impossible, and the recently introduced legal institution of managed entry agreement does not have the legal nature of compulsory licensing – it does not limit the patent rights of holders to medicines.

Key words: compulsory licensing, medicines, patent, property rights of patent owner, temporary restriction of patent rights.

1. Introduction

Research relevance. Human rights to life and health remain the highest social values and benefits in Ukraine and the world, as proclaimed in major international human rights treaties and the constitutions of many states. Life quality and expectancy are of paramount importance. In this regard, it should be noted that according to the UN, over the past 70 years, the global average life expectancy has increased by 23 years, which is mainly due to medical advances (UN, 2018). The invention of a vaccine for (black) smallpox based on

the cowpox virus, which had been described in detail in 1798 in the study by English physician and naturalist Edward Jenner “An Inquiry into the Causes and Effects of the Variolae Vaccinae, a Disease Discovered in Some of the Western Counties of England, particularly in Gloucestershire, and Known by the Name of Cow-pox (Jenner, 1798), was a considerable step towards the human struggle for life using medicines. Since that time, medicine has continued to develop, offering the advanced means to overcome and prevent diseases. Thus, it is difficult to overestimate the significance of medicine,

vaccination, and pharmaceuticals to save people's lives, improve their condition, and increase their duration.

At the same time, modern medical and pharmaceutical achievements are closely related to intellectual property rights, which are driven by a high level of commercialization of these industries in the world and the need to protect property and personal intellectual non-property rights in the relevant field. The rights of inventors of pharmaceutical products are often protected within the patenting institute. In addition, it is possible to protect medicines as objects of copyright that, according to A. O. Kodynets, is less effective, since it protects the form of expression of the creative result, not the chemical composition of a medicinal product, and does not extend to the application technique or the production of a substance (Kodynets, 2016, p. 167).

Patenting of medicines also takes place in our country. The Law of Ukraine "On Medicines" consolidates the right of authors (co-authors) of a medicinal product to obtain a patent by applying to the central executive body that implements state policy on intellectual property (Verkhovna Rada of Ukraine, 1996).

Moreover, it is socially important for each state to guarantee a possibility to use medicines with certain temporary violations of patent rights in "emergency" cases stipulated by law, when it is a choice between life and death, or the state economic security and the property rights of a patent holder. Such a mechanism in the world system of legal regulation of intellectual property relations – the article's case study is a medicinal product – is called *compulsory licensing*, although there are other related terms.

Subject novelty. The issue of compulsory licensing of pharmaceuticals was studied by N. P. Baaji, O. V. Basay, I. P. Volynets, O. Yu. Kashentseva, T. Yu. Klochko, A. O. Kodynets, O. O. Ponomaryova, et al. However, most studies of the above authors were carried out before 2020 and hence, they did not take into account new life realities associated with the rapid spread of coronavirus in the world, the need to make new flexible and operational decisions in terms of providing public access to medicines. Therefore, the institute under consideration has gained new and even greater social significance in the context of the global fight against the COVID-19 pandemic.

The purpose of this article is to study the mechanism of temporary restriction of proprietary patent rights to medicines, which is called "compulsory licensing"; the research task is to analyze the national and international experience of temporary restriction of patent rights while implementing the procedure of compul-

sory licensing of medicines. The research methodology relies on general scientific and special methods of cognition; the comparative law method, which allows comparing the domestic and international experience of legal regulation of compulsory licensing of medicine, plays an important role in the research process.

2. Definition of the concept of "compulsory licensing"

According to World Trade Organization terminology, several related terms mean, in their essence, compulsory licensing of medicines. Thus, the most common term is "*Compulsory Licensing*", when the authorities license companies or individuals other than the patent owner to use the rights of the patent – to make, use, sell or import a product under patent (i.e., a patented product or a product made by a patented process) – without the permission of the patent owner (Navarro, Vieira, 2021, p. 3). This term is widely used in foreign legal literature and regulations that will be further clear in the article text.

"*March-in Rights*", which was introduced by the Beye-Dole Act of 1980, is a kind of compulsory license and used exclusively in the United States. It allows the U.S. Federal Agency to interfere with owners' rights to patented inventions created with federal funding assistance. Should this request for a license be denied, the Federal agency may issue a compulsory license. In this case, the government uses the invention free of charge, in particular, by granting a non-exclusive, non-transferable, irrevocable, paid-up license that permits using the patented invention by the Government itself or on its behalf anywhere in the world (Navarro, Vieira, 2021, p. 3).

"*Government Use*" means the procedure or process under which the government uses a patented product on its own or by authorizing others to use the rights to the patented product for state or public purposes without the permission of the patent holder (Navarro, Vieira, 2021, p. 3).

Ukrainian legislation lacks a concept of compulsory licensing even though such a legal institution is enshrined in Ukraine at the regulatory level.

As O. Yu. Kashyntseva notes, domestic legislation now provides three legal mechanisms ensuring access to innovative and generic medicines capable of mitigating the patent monopoly on the latter: managed entry agreements (MEAs), defined in Art. 79-1 of the Fundamentals of the Legislation of Ukraine on Health Care; compulsory licensing of inventions relating to medicinal products enshrined by Art. 30 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models"; the use of a patented medicinal product

in the form of its generic version in the interests of the state in emergency cases following Art. 31 of the Law of Ukraine “On Protection of Rights to Inventions and Utility Models” (Kashyntseva, 2020, p. 36). It should be emphasized that the author’s position on the first paragraph is quite controversial. According to Article 79-1 of the Fundamentals of the Legislation of Ukraine on Health Care, the central executive body, which ensures the development and implementation of state policy on health care, authorizes a person to carry out healthcare procurement on his/her own initiative or on its behalf, and the person is entitled to conclude a managed entry agreements with the applicant on the initiative of the marketing authorization holder or its authorized representative (applicant) in order to maintain the availability of relevant medicinal products for patients at budget expense (hereinafter referred to as “a managed entry agreement”) (Verkhovna Rada of Ukraine, 1992). The content of the mentioned norm and the provisions of the Negotiation Procedure on Managed Entry Agreements and the Procedure for Conclusion, Execution, Amendment and Termination of Managed Entry Agreements approved by the Resolution of the Cabinet of Ministers of Ukraine No. 61 dated January 27, 2021 (Cabinet of Ministers of Ukraine, 2021), do not indicate the availability of any restrictions of patent rights to medicinal products, since it is stipulated only the contractual relationship between the state represented by the entitled state authorities as the buyers of specific medicinal products and the marketing authorization holders of the original (innovative) medicinal product as its suppliers. This procedure excludes any coercion or restriction of the rights of the patent holder to a medicinal product, although it provides citizens with access to certain medicinal products because they are purchased for budgetary funds.

The restriction of patent rights to medicines in Ukraine can occur within the legal institution of compulsory licensing, the legal basis of which is the above-mentioned Laws of Ukraine “On Medicines” and “On the Protection of Rights to Inventions and Utility Models”. At the same time, Article 9 of the Law of Ukraine “On Medicines” stipulates that in order to ensure the public health when registering a medicinal product, the Cabinet of Ministers of Ukraine may allow an authorized person to use a patented invention (utility model) related to such a medicinal product without the consent of the patent holder, although the relevant law was not adopted, only the resolution of the Cabinet of Ministers of Ukraine “On Approval of the Procedure for Granting Permission by the Cabinet of Ministers of Ukraine to Use a Patented Invention

(Utility Model) Relating to a Medicinal Product” dated 04.12.2013 No. 877 (Cabinet of Ministers of Ukraine, 2013).

The lack of proper legal regulation of the issue under study blocks the implementation of the mechanism of compulsory licensing of medicines in Ukraine and necessitates its improvement. In this regard, it is apt to discuss specific international and foreign practices.

3. International and foreign experience of temporary restriction of patent rights to medicines

The legal grounds for the temporary restriction of patent rights were first laid by the Paris Convention for the Protection of Industrial Property of 20.03.1883, which enshrines the right of each country of the Union for the Protection of Industrial Property to take legislative measures providing for the issuance of compulsory licenses to prevent abuses that may arise from the exercise of the exclusive right granted by the patent (League of Nations, 1883). An important document of the World Trade Organization, which defines the legal grounds for temporary limitation of patent rights, is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which is the 1C annex to the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco, on 15.04.1994. The TRIPS Agreement was amended by the Protocol dated 06.12.2005, which entered into force on 23.01.2017. The mentioned protocol supplemented the Agreement with Article 31bis and an annex, which determined, in the context of compulsory licensing of medicines, the peculiarities of limiting patent rights to manufacture and export pharmaceutical products (pharmaceutical product) for countries that cannot manufacture them in sufficient quantities for their patients (World Trade Organization, 2017).

The Doha Declaration, adopted in 2001 at the WTO annual ministerial meeting in Doha, Qatar, is also an essential international instrument in this area. The Declaration affirmed the primacy of health over commercial interests and reaffirmed the members’ rights to use TRIPS guarantees, such as compulsory licenses, to overcome patent barriers in order to promote access to medicines (World Trade Organization, 2001).

The above documents have led to the development of relevant legislation in many countries. Thus, in Germany, patent law, namely section 24 of the German Patent Act, is the legal basis for compulsory licensing of pharmaceutical products. The German Patent Act meets the requirements of the Agreement on Trade-Related Aspects of Intellectual Property

Rights (TRIPS) and the implementation of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. A request for a compulsory license may also arise from the provisions of competition law and Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. (Martinez, 2021). In this case, the issuance of a compulsory license does not mean the use of the invention free of charge, an adequate royalty, which is standard for commercial practice, is paid. In event of a dispute between the parties, the Federal Patent Court determines the amount of royalties at the parties' request (Höhne, 2019).

In the US, as previously noted, compulsory licensing is stipulated by the "March-In Rights" legal institute introduced by the Beye-Dole Act of 1980. The U.S. government is entitled to "march-in rights" if a patent holder has failed to take steps to: practically apply the invention; reasonably meet the health and safety needs of the country; reasonably comply with the general use requirements defined by federal regulations; or granted the exclusive right to use the patented invention to a third party without obtaining a binding promise that the invention will be substantially manufactured in the U.S., or if the licensee breaches the promise (Shah, 2021).

In China, compulsory licensing of patented medicines was stipulated by the *Patent Law of the People's Republic of China* in 2008, after introducing specific amendments authorizing the issuance of compulsory licenses for the manufacture of medicines and their export to countries and regions under the international treaties of China. In general, the legal basis for compulsory licensing in China is quite complex and is represented by legal documents of different legal effects, such as *Implementing Rules of the Patent Law of the People's Republic of China* of 2010, *Measures on Compulsory Licence of Patent Exploitation* of 2012, *Opinions of the General Office of the State Council on Reforming and Improving Policies on the Guaranteed Supply and Use of Generic Drugs* of 2018, and others (CMS, 2021).

In the United Kingdom, compulsory licensing is regulated by the *Patents Act 1977*. According to the regulation, the grounds and procedure for obtaining compulsory licenses vary depending on whether the patent holder belongs to the World Trade Organization member states or not. For example, in the former case, the grounds for granting a compulsory license under Article 48a are: 1) the patented inven-

tion is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms; 2) by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms – (i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or (ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;; 3) by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced (Intellectual Property Office, 1977).

In France, matters of compulsory licensing, in addition to the international documents defined above, are regulated by separate sections of the French Intellectual Property Code. The grounds for granting a compulsory license in France may be: 1) insufficient use of the patent by its holder; 2) the impossibility of using the patent by the patent holder without infringing the previous patent in case of impossibility of voluntary obtaining a license from the holder of the previous patent, provided that the invention is of significant technical advance or is of great economic interest; 3) protection of the interests of the national economy or national security (CMS, 2020).

4. Compulsory licensing in the fight against coronavirus disease (COVID-19)

In the fight against coronavirus disease (COVID-19), governments of some countries of the world have adopted regulations aimed at simplifying procedures for compulsory licensing. For example, in March 2020, the German government amended a set of legislative acts focused on simplifying the procedure for compulsory licensing of pharmaceuticals. In particular, section 5 of the German Infection Protection Act was modified to consolidate that all inventions of pharmaceuticals and medical devices necessary for disinfection and laboratory diagnostics are used in the interests of public welfare or safety. Moreover, it was adopted the Law on the Prevention and Control of Infectious Diseases which granted the Federal Ministry of Health powers that allow issuing a compulsory license and enshrined the legal basis for limiting drug patents. At the same time, the party initiating obtaining a compel-

sory license must prove the existence of two circumstances: 1) within a reasonable period of time, the party tried to obtain permission from the patent holder to use the invention on reasonable commercial terms; 2) obtaining a compulsory license is conditioned by the public interest (Martinez, 2021).

In addition to Germany, similar legislative changes have been introduced in Australia, Brazil, Canada, Chile, Colombia, Ecuador, Hungary, Indonesia, and Russia (Access Campaign, 2021, p. 4-5). Hungary, for example, even implemented the procedure for issuing a compulsory license for Remdesivir. The Hungarian company Richter, to which the government requested to ensure domestic manufacture of the drug during the first wave of the pandemic, obtained a compulsory license (Access Campaign, 2021, p. 5).

In March 2020, Israel became the first government to grant a compulsory license for antiretroviral therapy drugs lopinavir/ritonavir, which were undergoing testing and repurposing for treating COVID-19. Israel granted a compulsory license and addressed the manufacturer of alternative generic drugs from India because the patent holder, AbbVie, was unable to secure sufficient supplies of Lopinavir/Ritonavir at the time (Access Campaign, 2021, p. 5).

5. Conclusions

The following can be highlighted as the research findings:

- states in their interests and the interests of society provided for the legal possibility of temporary restriction of property rights of patent holders, incl. to medicines, long ago;

- the settlement of the procedure for compulsory licensing of medicines varies significantly; the legal regulation of these relations is most often conducted by general patent norms. However, against the background of the ongoing COVID-19 pandemic around the world, some countries have begun to introduce special legal regulations of the procedure for temporary restriction of patent rights in terms of compulsory licensing of medicines;

- in Ukraine, the institute of compulsory licensing of pharmaceutical products is at the initial development – there is no proper legal regulation of relevant legal relations that makes its functioning impossible;

- areas of improvement of the legal regulation of compulsory licensing of medicinal products should be based on international instruments, i.e., the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Doha Declaration, as well as consider the experience of individual countries that are characterized by a proper legal regulation of the area concerned and practical implementation of procedures for the issuance of compulsory licenses (for example, France, Israel, Germany, the United Kingdom, and others).

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ТИМЧАСОВЕ ОБМЕЖЕННЯ ПАТЕНТНИХ ПРАВ В КОНТЕКСТІ ПРИМУСОВОГО ЛІЦЕНЗУВАННЯ ЛІКАРСЬКИХ ЗАСОБІВ: НАЦІОНАЛЬНИЙ ТА ЗАРУБІЖНИЙ ДОСВІД

Анотація. Мета. Метою статті є дослідження механізму тимчасового обмеження майнових патентних прав на лікарські засоби, який отримав назву «примусове ліцензування», на підставі аналізу національного та зарубіжного досвіду у цій сфері. **Методи дослідження.** Для досягнення мети дослідження застосовувалися загальнонаукові та спеціальні методи пізнання, особливе значення в процесі дослідження мав порівняльно-правовий метод, що дозволив порівняти досвід правового регулювання України та зарубіжних країн у сфері примусового ліцензування лікарських засобів. **Результати.** Досліджуються правові категорії, що позначають процедуру примусового ліцензування лікарських засобів в світовій практиці. Висвітлені питання міжнародно-правового становлення інституту обмеження патентних прав шляхом видачі примусових ліцензій в цілому, а також саме щодо лікарських засобів. Аналізується досвід окремих країн запровадження правового інституту примусового ліцензування лікарських засобів, зокрема, наводяться приклади США, Німеччини, Великої Британії, Франції, Китаю. Автором окремо висвітлено той факт, що примусове ліцензування лікарських засобів отримало новий поштовх до розвитку в контексті боротьби всього світу з пандемією COVID-19. Наводиться приклад ряду країн, в яких було прийнято спеціальне правове регулювання у вказаній сфері (Австралія, Бразилія, Канада, Чілі, Колумбія, Еквадор, Угорщина, Індонезія, Росія). **Висновки.** В результаті проведеного дослідження досвіду вказаних країн автором робиться висновок, що примусове ліцензування лікарських засобів використовується, в першу чергу, для захисту національних інтересів держави, зокрема економічних, а також з метою забез-

печення захисту здоров'я населення. На підставі аналізу чинного законодавства України автором робиться висновок, що інститут примусового ліцензування лікарських засобів знаходиться на стадії початкового розвитку, на сьогодні відсутнє належне правове регулювання цієї групи правовідносин, що унеможлиблює його функціонування, а запроваджений нещодавно правовий інститут договорів керованого доступу не є за своєю правовою природою примусовим ліцензуванням, ним не обмежуються патентні права власників патентів на лікарські засоби.

Ключові слова: примусове ліцензування, лікарські засоби, патент, майнові права власника патенту, тимчасове обмеження патентних прав.

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