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Application of Compulsory Licensing in the Context of the Covid-19 Coronavirus Pandemic

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ABSTRACT

The article reveals the features and legal grounds for the application of the mechanism of restriction of patent rights through compulsory licensing of inventions. The analysis of the legislation on the regulation of these relations is carried out. The EU experience in the use of compulsory licensing is analyzed and prospects for Ukraine are considered. Theoretical positions on the subject of research are analyzed. It is substantiated that in emergency situations the state should defend the public interests to the detriment of the interests of the patent owner and may apply a compulsory license. Compulsory licensing is a common practice and an important legal institution.

The conditions and features of granting a compulsory license for objects of patent law in accordance with the provisions of Ukrainian legislation are revealed. The terms of the compulsory license are not based on the mutual consent of the licensor and the licensee but are determined by the competent state body. The correlation of the Ukrainian legislation with the international obligations of Ukraine is investigated. Analysis of foreign sources shows that compulsory licensing is one of the effective mechanisms for reaching a compromise between the public interests and the patent owner. The paper confirms the expediency of shifting the balance of interests from the patent owner to society in the context of the COVID-19 pandemic. Recommendations for improving Ukrainian legislation are provided.

Keywords: Public interest, medicines, patent rights, patent owner, results of scientific and technical creativity, health care, availability of medicines, compulsory license, balance.

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INTRODUCTION

The existence of modern world needs in the context of the COVID-19 coronavirus pandemic and global political and social processes significantly affect the formation of tendencies in legal systems and individual legal institutions. The sphere of protection of intellectual property rights, protection of rights to the results of intellectual, creative activity, and means of individualization did not remain outside these processes. It is especially true regarding such an important issue as ensuring the availability of new, vital technologies for society and protecting the rights of their right holders.

Patent law is part of intellectual property law which provides legal protection, especially the private interests of creators (inventors, authors) and patent owners of scientific and technical results in any field of technology, their subjective non-property and property interests. Thus, patent law not only stimulates the development of invention but also carries the risk of excessive monopolization, which is rather detrimental to the innovative and social development of the country. At the same time, the objects of patent law, as well as other objects of intellectual property law, play an important role in economic, scientific, and technical (innovative) development of society, whose members are interested in access to new technologies and the free exchange of information. Therefore, of particular importance is the creation of a legal basis for ensuring the public interest by establishing an optimal legal mechanism for maintaining a fair balance of public interests and patent owners. One of the legal means of ensuring the balance of public interests and patent owners is the restriction of the patent monopoly, namely through the mechanism of compulsory licensing which is applied in case of non-usage or incomplete usage of the scientific and technical solution protected by the patent and is designed to prevent (or mitigate) the situation of incomplete satisfaction of society's needs in goods or services protected by the patent.

The problem research status. Some issues of patent and legal protection of the results of scientific and technical creativity, their features, and procedure were studied in separate scientific publications, both native and foreign scientists. Among them are such researchers as V. Bazylevych, J. Boyle, A. Vorozhevych, O. Kashintseva, O. Kartschiya, A. Latyntsev, V. Potekkhin, L. Rabotyagov, R. Sitdikov, N. Shakunov, and others. Yet, the need for a separate study of problematic issues to determine the limits and restrictions of patent rights does not lose its relevance to this day. This is especially true of the legal basis for the application of the mechanism of compulsory licensing of inventions relating to medicinal products.

The aim and objective of the research. The aim of the article is to clarify the contradictory legal aspects of the functioning of the patent protection system in the context of modern globalization processes and to find the optimal regime of protection of rights to scientific and technical results of intellectual and creative activity. The objective of the article is to study the legislative possibilities for restricting patent rights to achieve a balance of public interest and patent owners through the usage of compulsory licensing and to substantiate proposals to improve the legal regulation of the studied relations.

Opening and development of a real land market in the countries of Central and Eastern Europe – Bulgaria, Poland, Moldova, Romania, Russia, Estonia, Latvia, Lithuania, the Czech Republic, Slovenia, Ukraine, etc. – is a complex issue because, on the one hand, it is

conditioned by its organizational, technical and financial character and, on the other hand, it is one of the most complicated social problems that cannot be solved by means of adoption of laws, regulations or orders only. These issues require, first and foremost, political will, reasonable internal legal support, powerful specialized financial institutions, ratification of foreign international investment programmes. This is the financial and economic model of the land market reforming and its further development, creation of small and medium-sized farm enterprises, their financial, methodological and organizational support that is professed by the countries of Central and Eastern Europe analyzed in this article. The article emphasizes that the credit and land policy of the countries of Central and Eastern Europe is being formed not only on the basis of purchase and sale of land but, first and foremost, on the basis of its lease, cultivation and processing of agricultural products, purchase of agricultural equipment with adequate guarantees regarding the reasonable utilization of credit resources and their timely repayment on the part of guarantee funds that just as banks affect not only the investment climate but also the national land policy in the sphere of agrobusiness which is one of the key issues in terms of development of a socially oriented market economy where a reasonable balance between private and public interests is the optimal ratio between the self-organization of private industry and its economic efficiency.

The investigation of issues related to the reforms and development of the land market and together with this its multi-source credit financing in order to accelerate the development of the agro-industrial complex was conducted by the following specialists: L. Harvey (the USA, 1974), J. Hopkins (the USA, 1979), N. Kozyrin (England, 1995), D. Porbe (the Netherlands, 1996), Separvati (Indonesia, 2003), V. Vlasov (Poland, 2005), M. Korobeynikov (Russia, 2010), O. Melnyk (Ukraine, 2013), V. Anisimov (Ukraine, 2015), O. Zubrytskyi (Ukraine, the Netherlands, England, 2017), O. Lemishko (Ukraine, 2019).

MAIN TEXT

The understanding of the system of limits and restrictions of patent rights in terms of their impact on the innovative development of society as a whole has been further developed. The legal mechanism for restricting patent rights to achieve a balance of public interests and patent owners through the application of a compulsory license has been defined. Proposals for improving the legal regulation of the studied relations have been substantiated.

The basis of the methodology of research of the chosen problem comprises a systematic approach, as well as dialectical, formal-logical, and structural-functional methods and other general scientific research methods, as well as special legal methods: comparative law and formal law.

Presentation of main material. For the last almost fifty years, the global COVID-19 pandemic can be called one of the most significant events that have affected all sectors of the Ukrainian economy without exception. COVID-2019 and measures to prevent its spread have identified a number of problems not only in public administration, social security, health care, etc. but also in the exercise of rights.

Patent rights are an almost unrestricted legal monopoly on the use of the results of scientific and technical creativity. Nevertheless, how significant can be the influence of the owner of the exclusive right on the technical and intellectual development of society in a pandemic COVID-19? And in general, is it possible to limit the rights to the result of intellectual, creative activity, taking into account the public interests?

The increase in drug and vaccine development during the COVID-19 pandemic has increased interest in patent rights as a legal monopoly. Nevertheless, the existence of absolute legal protection of patent rights will inevitably lead to a conflict of interests of right holders with the public interests. And, therefore, it is important to establish a legal mechanism to ensure a fair balance of public interests and patent owners.

It is possible that drugs and coronavirus vaccines are in the final stages of clinical trials, and some are already suitable for usage. Yet, the very fact of their existence does not guarantee that society will be able to freely access new, vital technologies (especially in the medical and pharmacological spheres) if governments do not overcome the system of patent monopoly in the pharmaceutical industry. The COVID-19 pandemic will end in the same way as any other: drugs and vaccines will be buried under patents [1]. Patents are the most valuable asset of pharmaceutical companies and it can be assumed that the COVID-19 pandemic will lead to their significant growth, as it is extremely important for patent owners to obtain exclusive rights to the invention for further commercialization. The COVID-19 vaccine and medicines are profitable and big business. And it is the pharmaceutical companies (big pharmas) that will decide who will have access to medicines and vaccines because the patent monopoly on the use of scientific and technical results can limit and prevent access to new technologies to other members of society. Today, this problem already exists in the medical and pharmaceutical industries. Accordingly, the clash of private interests (creators, inventors, patent owners) and public interests is inevitable.

Sorry as it may be, there are examples of how patent owners (big pharmas) are able to restrict access to COVID-19 drugs. Thus, the multinational company ZM has more than 400 patents for respiratory protection (respirator N95, surgical masks, gowns, and gloves), and strictly limits the number of people who can produce and supply them to any country. Thus, the 3M multinational company has more than 400 patents for respiratory protection (respirator N95, surgical masks, gowns, and gloves), and strictly limits the number of people who can produce and supply them to any country. These PPEs protect doctors, nurses, and other healthcare professionals from COVID-19 during the treatment of patients who are constantly in short supply. At the same time, the governments of a number of countries have repeatedly called on the 3M big pharma to open its patents during the pandemic to increase production. Nevertheless, the latter is in no hurry to take such a step, as they clearly understand that they will lose over a million in profits. Of particular interest is the situation with the supply of a French manufacturer of diagnostic tools, which submitted a test kit to the US Food and Drug Administration (FDA) for emergency permission to sell it. However, they were sued by the pharmaceutical company Softbank in regard to a possible case of infringement of patent rights [2]. At present, the most effective drugs used in the treatment of COVID-19 are already patented, namely, favipiravir, which is used to treat influenza, as well as a mixture of lopinavir and ritonavir, which is sold

under the brand name Kaletra for the treatment of HIV/AIDS. For example, remdisivir, an Ebola drug from biotechnology company Gilead, is limited by a patent until 2038. Gilead has recently claimed the orphan drug status for Remdesivir because of its potential benefit in the treatment of COVID-19. The orphan drug status gives the company government support in developing drugs for rare diseases, the production of which would otherwise be unprofitable. However, COVID-19 is not a rare disease [1], although it is dangerous. In such a difficult environment, pharmaceutical companies (patent owners) still avoid the issue of opening patents for free usage in all countries.

As an example of profiting from a pandemic, let us note the case of the American test manufacturer named Cepheid. Cepheid has just received an emergency license from the Food and Drug Administration (FDA) to use a rapid test for the SARS-CoV-2 coronavirus, which gives results after 45 minutes. Such an analysis requires existing tools that are already used to diagnose tuberculosis, HIV, and other diseases. However, Cepheid announced that in developing countries, including the poorest countries, where people live on less than two dollars a day, the cost of the test will be $19.8 USD. Médecins Sans Frontières (MSF) and other organizations conducted a study of the Cepheid tuberculosis test, which uses a similar cartridge system for diagnosing tuberculosis, which costs $10 in developing countries. It turned out that the cost of each cartridge, including production, overhead, and additional costs, is only $3. So, each test can be sold for $5 without loss of profit.

It is not surprising that countries are taking or considering preventive measures to counter the patent monopoly in order to combat the COVID-19 pandemic, that is, to ensure the public interest. To reduce the negative consequences of the legal monopoly of patent rights, the legislation of most countries provides restrictions and exclusions from this legal protection, provided that such restrictions and exclusions do not create significant obstacles to the normal realization of intellectual property rights and exercising the legally protected interests of the subjects of these rights. Accordingly, in recent years, the need to strengthen the role of institutions that could be used to protect the public interests in the face of the latter with the interests of right holders in these difficult conditions is becoming increasingly important. An example of this institution is a compulsory license that will limit the patent monopoly in order to ensure the public interests in the extraordinary circumstances in which humanity is today.

It should be noted that the decision of the Constitutional Court of Ukraine clarified that "constitutional rights and freedoms of man and citizen may not be restricted, except as provided by the Constitution of Ukraine" (Part 1 of Article 64 of the Constitution of Ukraine) [3]. Yet, it is stated that the establishment of restrictions on human and civil rights and freedoms shall be permissible only if such a restriction is moderate (proportional) and socially necessary. It is obvious that exceptions, limits, and restrictions are crucial for any system of legal protection. It is an effective system of exceptions, limits, and restrictions that allows reconciling the interests of creators, patent owners, and users of the results of intellectual and creative activity, thus ensuring a fair balance between access to protected results of intellectual, creative activity, and their legal protection.

In conditions of a certain conflict of interest (access to medicines in the context of the COVID-19 pandemic), there is a high probability that the patent owner may exercise their rights contrary to the public interest. Patent owners invest heavily in the search for effective drugs for coronavirus, because the main profit will be for the manufacturer who will be the first to offer the most effective drugs to society (of course, after undergoing the necessary procedures and obtaining a patent). Accordingly, pharmaceutical companies, as right holders, in order to ensure a privileged (exclusive) position and prevent uncontrolled reproduction (in the case of generics) and the dissemination of counterfeit patented drugs (drugs, vaccines), will prohibit, restrict, and prevent access to the usage of the results of scientific and technical creativity in the field of medicine and pharmacology to others, for example, by setting knowingly high prices or failing to grant a permit (license) or by setting unfair conditions for concluding a contract. Thus, the right holder may determine the methods, territory, term of use of intellectual property rights, the number of royalties, which may lead to the prohibition of any use by third parties. Another thing is that the prohibition, in this case, is implemented not by refusing to grant licenses but by establishing difficult conditions for overcoming it.

It should be noted that in case of refusal to grant a license (permission) to use the patented result of scientific and technical creativity, the true purpose of the rights holder is quite difficult to determine. Although the general consequence of abuse of rights – refusal to protect the right – does not apply to such actions of the patent owner. Thus, it is necessary to ensure a balance of private and public interests in relation to patented results of scientific and technical creativity, i. e. the legislator or law enforcers should compensate the will of the patent owner by granting access on fair terms to scientific and technical results to other entities, and not refusing to protect the exclusive right. It is difficult to ensure proper protection of the human right to life and health, and in connection with the patent monopoly, the modern legal doctrine of intellectual property law provides a mechanism to influence the exercise of exclusive rights by issuing a compulsory license to the results of scientific and technical creativity, including in the field of health care, for the purpose of their non-commercial usage by an authorized subject (government or court).

According to the World Health Organization, the concept of "availability of medicines" is considered in terms of physical and economic availability. Physical availability involves providing consumers with quality effective and safe medicines. Economic availability includes a system of state regulation of prices and demand for medicines [4, p. 4]. The COVID-19 pandemic is creating unprecedented demand for personal protective equipment (masks, respirators, gloves, protective suits, antiseptics, etc.), air purification and disinfection systems, and disease treatment (lung ventilation systems, drugs, vaccines, etc.). Every member of society has the right to access medical treatment, and it is the state that must ensure that it is not only available but also accessible to everyone.

At the same time, in case of violation of the exclusive (property) rights of right holders to the results of scientific and technical creativity, the law provides for liability. However, during a pandemic, the situation with the protection of patent rights for developed drugs, tests, and vaccines must change in the direction of weakening. Thus, governments may or may not decide to manufacture and distribute such personal protective

equipment (masks, respirators, gloves, protective suits, etc.), air purification and disinfection systems, and disease treatment (lung ventilation systems, drugs, and vaccines) without obtaining the necessary permission of the patent owner. This is usually done through the use of a compulsory license.

Compulsory licensing in the field of medicine and pharmaceuticals is connected not only with patent law but also with human rights. Many constitutions recognize the human right to the highest attainable standard of health (mental and physical), and it is enshrined in Art. 25 of the Universal Declaration of Human Rights. It is obvious that access to medicines is one of the key factors in the exercise of the right in question and should not be hindered by the interests of the patent owner. The UN High Commissioner for Human Rights has acknowledged that there is a clear conflict between the regime of intellectual property rights embodied in the TRIPS Agreement, on the one hand, and internationally recognized human rights, on the other hand. Thus, states can use compulsory licensing in the field of public health; distribute medicines to needy citizens free of charge as part of their health improvement programs, which makes such use non-commercial [5, p. 364-365].

Accordingly, compulsory licensing is an important tool that can protect the public interests from patent owners who set unfair terms in licensing agreements, evade licensing, or sell their products on fair terms. Compulsory licenses are an extremely serious tool, the consequences of which must be comprehensively assessed in both the short and long term. Nowadays, it cannot be unequivocally stated that the mechanism of such licensing contributes to achieving the goals of increasing the availability of medicines for the population. However, it is compulsory licensing that should ensure the balance of public interests and the patent owner, that is, to prevent a situation where the public need for medicines will remain unmet due to restrictions by the patent owner [6].

At the same time, the institution of compulsory licensing fully corresponds to the peculiarities of patent relations and does not deprive the patent owner of the protection of his exclusive right, nor does it prevent them from independently using and effectively commercializing the development. In addition, such a license is paid, although granted against the will of the patent owner, is a means of securing his property interests.

It is likely that there will soon be a significant increase in the use of compulsory licenses for scientific and technical work, especially in the field of health care, for their non-commercial usage for the treatment of the COVID-19 coronavirus. In the current international legal doctrine of intellectual property rights and in most national laws [7], this legal mechanism allows governments to temporarily limit the legal protection of patent rights by compulsory licensing in favor of specially designated persons or institutions. This institution is to be applied precisely in those cases when the harm to the public interest from the exercise of the exclusive patent right exceeds the benefits received by the right holder [8]. The Chilean government recently stated that the pandemic justifies the usage of private (compulsory) licensing. Israel has issued private (compulsory) licenses for lopinavir and ritonavir. In March 2020, Israel, despite its patent protection, authorized the import of a generic version of lopinavir/ritonavir. Ecuador has approved a resolution calling on the Minister of Health to issue private (compulsory) licenses for all patents related to COVID-19. Canada and Germany have amended their patent laws to ensure the speedy granting of a compulsory license [9]. Thus, the German government intends to adopt amendments to the German Law on the Prevention and Control of Infectious Diseases (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen - Infektionsschutzgesetz - IfSG), which may also have consequences for patents. They state that in a pandemic, certain patents must be used in the public interest or in the interests of the security of the Federal Republic of Germany, with the permission of the Federal Ministry of Health and in accordance with section 13 (1) of the Patent Law (Patentgesetz - PatG).

Brazil is in the process of amending its patent law to simplify compulsory licensing [10].

Costa Rica has actually submitted a proposal to the World Health Organization to create a global technology pool of COVID-19 – a place where all the necessary intellectual property, such as patents, designs, trade secrets, and software, could be combined. Politicians in the Netherlands and the United Kingdom have recently supported this idea, and the WHO Director-General has welcomed Costa Rica's proposal, while UNITAID has promised to fund it [1].

The history of the use of compulsory licenses in patent law to protect the public interests and protect public health is many years old. Although the United States at the international level denies the need to expand the grounds for issuing a compulsory license [11, p. 3] and uses threats of trade sanctions to pressure these countries to waive compulsory licensing. In the country itself, this practice has existed since 1941 [12]. Since 1950, the practice of compulsory licenses has also existed in Great Britain [13]. Many countries, including the United States, issue compulsory licenses to ensure the public interest or overcome the effects of anti-competitive practices [14]. In general, there are many examples of countries using a compulsory licensing mechanism in the pharmaceutical sector.

The Paris Convention for the Protection of Industrial Property [15] in Art. 5 establishes the right of each Member State to take legislative measures to grant compulsory licenses in order to prevent abuses that may arise from the exercise of the exclusive right conferred by a patent. Directly the TRIPS Agreement in Art. 31 provides for the right to use a patent without the permission of the patent owner by the government of the member state or a third party with the permission of the government in case of an emergency in the country or in other circumstances of extreme necessity [16]. In fact, the term "compulsory licensing" as such is not used in the TRIPS Agreement. Instead, in Art. 31 of this Agreement, the legal structure, which is translated into Ukrainian as another use (invention) without the consent of the right holder, is provided. There are also provisions on the basis of which a compulsory license can be issued: in the case of public health, environmental safety, and other public interests. It is established that an interested person who intends to use a patented invention (utility model) to ensure the health of the population, must apply to the owner of such an invention (utility model) with a request for voluntary licensing. The TRIPS Agreement does not contain restrictions on the grounds for compulsory licensing. Therefore, each country has the right to develop its own compulsory licensing regime, which will allow, under certain conditions or to achieve strategic goals, the production or import of patented drugs and their generic versions.

According to Art. 31 of the TRIPS Agreement, compulsory licenses must be granted to meet the needs of the domestic market of the country issuing such a license. Countries with overcapacity were generally not allowed to export drugs manufactured under compulsory licenses. In the case of compulsory licensing, the patent owner must receive adequate compensation. However, according to the TRIPS Agreement, there are no criteria for determining sufficient compensation, i.e. the agreement leaves this issue to the discretion of each country. The decision to issue a compulsory license and the amount of compensation may be reviewed in court or otherwise. According to Art. 31 (k) of the TRIPS Agreement, the amount of compensation to the patent owner is determined taking into account the amounts established for violations of anti-competitive law. The TRIPS Agreement provides for the issuance of a compulsory license without prior negotiations with the patent owner as a precaution against anti-competitive practices in accordance with the provisions of Art. 31 (b) of TRIPS. The decision to recognize anticompetitive actions must be made administratively or judicially in accordance with the legislative procedure. It should be noted that in the framework of this procedure there is prior notice of the patent owner. The TRIPS Agreement provides for a number of restrictions on the volume of production and duration of use of a compulsory license (Article 31 (c)), as well as the revocation of a license (Article 31 (g)). The right to use a patent should not be exclusive (Article 31 (d)) and should not be assigned to any third party (Article 31 (e)). The patent owner has the right to apply to a judicial or administrative authority for the revocation of a compulsory license (Article 31 (g)).

In order to implement these provisions, the Doha Declaration on the TRIPS Agreement and Public Health was adopted [17]. In addition, the Declaration identifies the importance of implementing and interpreting the TRIPS Agreement in the most appropriate way to protect the public interest – by making available to the public existing medicines and creating conditions for the production of new ones. It is also stated that the provisions of this declaration do not and should not contradict the right of member states to take appropriate measures to protect the health of the population. Nevertheless, the status of the declaration is not defined today, so the question of its legal force is controversial in WTO law [18]. In fact, the declaration can be seen as a political intention and a choice of further course, which is not legally binding [19]. At the same time, the declaration states that each country independently determines the grounds for the application of the compulsory licensing procedure. It is stipulated that the application of the compulsory licensing procedure does not necessarily have to be an emergency. The states themselves determine the circumstances that they consider extraordinary, that is, it is the state (represented by the authorized bodies) that determines what circumstances in the field of medicine are the basis for the issuance of a compulsory license.

The Directive 2001/83/EU on the Community code relating to medicinal products for human use of 06.11.2001 and Regulation (EC) (816/2006 "On compulsory licensing of patents relating to the manufacture of medicinal products for export to countries with health problems" sets out the main purpose of any rules governing the production, distribution, and usage of medicinal products, namely the protection of public health (Article 1 (2)). The main criteria for the use of the compulsory licensing mechanism by the state as a means of ensuring access to treatment are the availability of relevant economic indicators, membership of states in the WTO, and the Organization for Economic Cooperation and Development (OECD). The subject of compulsory licensing of rights can be both the rights defined in the patent and the rights that have been extended in accordance with the Supplementary Protection Certificate (Article 2 of EU Regulation №816/2006).

Another international legal act should be mentioned, namely the Association Agreement between Ukraine and the EU. Thus, Art. 212 of the Association Agreement provides for the protection of inventions in the field of biotechnology [20], and Part 11 of Art. 212 refers to mandatory cross-licensing. In Art. 219 of the Association Agreement, the parties also recognize the importance of the aforementioned TRIPS Agreement and the Doha Declaration.

The legal basis for the issuance of a compulsory license for a patented medicinal product is currently Part 3 of Article 30 and Part 2 of Article 31 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" [21], Article 9 "On Medicines" [22], Resolution of the Cabinet of Ministers of Ukraine of 14.01.2004 № 8 "On Approval of the Procedure for Granting Permission by the Cabinet of Ministers of Ukraine to Use the Patented Invention (Utility Model) or Registered Topography of Integrated Circuit" [23], and Resolution of the Cabinet of Ministers of Ukraine of 04.12.2003 № 877 "On Approval of the Procedure for Granting Permission by the Cabinet of Ministers of Ukraine to Use the Patented Intention (Utility Model) concerning Medicines [24].

According to international and national law, there are two grounds for issuing a compulsory license for a patented medicinal product as a result of scientific and technical creativity: Part 3 of Article 30 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models", where in order to ensure public health, state defense, environmental safety, and other public interests, the Cabinet of Ministers of Ukraine may allow the use of a patented invention (utility model) to a person designated by him without the consent of the patent owner; Part 2 of Article 31 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models", which does not recognize the violation of rights arising from the patent, the use of patented inventions (utility models) in emergencies (natural disaster, disaster, epidemic, etc.) by notifying the patent owner as soon as it becomes practicable and paying them the appropriate compensation. However, the first case is more interesting for our research.

Thus, the introduction of compulsory licensing of medicines at risk of significant shortages of personal protective equipment, air purification and disinfection systems, and treatment of disease in Ukraine caused by the situation with the COVID-19 pandemic is one of the limitations of patent rights and, as we see, is technically possible. In this case: 1) permission for such usage is granted based on specific circumstances; 2) the scope and duration of such usage are determined by the purpose of the granted permit; 3) permission for such use does not deprive the patent owner of the right to grant permits for the usage of the invention (utility model) to other persons; 4) the right to such usage is not transferred, except in the case when it is transferred together with that part of the enterprise or business practice in which this use is carried out; 5) use is allowed mainly to meet

the needs of the internal market; 6) the patent owner is notified of the granting of permission to use the invention (utility model) as soon as it becomes practically possible; 7) the permit for use is revoked if the circumstances due to which it was issued cease to exist; 8) the patent owner is paid adequate compensation in accordance with the economic value of the invention (utility model) [21].

Accordingly, a compulsory license can be granted only in the event of circumstances (pandemic COVID-19) that pose a threat to the health of the population of Ukraine, national defense, environmental safety, etc. In this case, the scope and duration of use of patent rights under a compulsory license are determined by the purpose of the permit (for the period of the COVID-19 pandemic). Therefore, at the end of the COVID-19 pandemic, such a compulsory license shall be terminated. It is important that the permit of the Cabinet of Ministers of Ukraine clearly defines the purpose of its provision and the criteria for establishing the presence (or absence) of the circumstances that led to its provision. In this case, the existence of an unjustified refusal of the patent owner to the applicant (user) to issue a license to use the invention (utility model) is not required, that is, the obligation to conduct preliminary negotiations with the patent owner to grant a commercial license has lost its topicality [41].

The granting of a compulsory license does not deprive the patent owner of his rights (ie the right to use the objects of patent law, the right to grant permission to use the objects of patent law to others, or the right to prevent the illegal use of objects of patent law). In this case, a person who has received the right to use the objects of patent law under a compulsory license may not transfer such right to another person, unless it is transferred together with the part of the enterprise or business practice in which such use is carried out. Compulsory licensing can be granted mainly to meet the needs of the domestic market (provision of medicines). A compulsory license is notified to the patent owner and adequate compensation is paid in accordance with the economic value of the objects of patent law.

However, the law does not specify the term and amount of compensation to patent owners. Also, we should pay attention to the use of the terms "compensation" and "reward" when issuing a compulsory license. Thus, in paragraph 8 of Part 3 of Art. 30 of the Law of Ukraine "On protection of rights to inventions and utility models", the patent owner is paid adequate compensation in accordance with the economic value of the invention (utility model), and in Part 3 we are talking about "reward". The reward is a payment for the economic value of the permitted use, but compensation is a broader concept and includes compensation for lost profits or losses caused to the patent owner in connection with such licensing. Thus, the term "reward" is more acceptable in use, and therefore needs to be clarified in law [40].

In addition to laws, we pay attention to bylaws. Thus, among the current bylaws, we shall note the Resolution of the Cabinet of Ministers of Ukraine of 14.01.2004 № 8 "On Approval of the Procedure for Granting Permission by the Cabinet of Ministers of Ukraine to Use the Patented Invention (Utility Model) or Registered Topography of Integrated Circuit" that determines the procedure for consideration of an application for granting permission to use a patented invention (utility model) or registered topography of integrated circuit without the consent of the owner of the patent (certificate) but with paying them compensation by the Cabinet of Ministers of Ukraine [23].

This Procedure determines the procedure for consideration of an application for granting permission to the Cabinet of Ministers of Ukraine to use a patented invention (utility model) without the consent of the owner of the relevant patent (certificate) but with paying them compensation. Such permission is granted in order to ensure public health, environmental safety, and other public interests. However, the resolution states that the effect of this Procedure does not apply to the procedure for granting permission to the Cabinet of Ministers of Ukraine to use a patented invention (utility model) relating to a medicinal product. Permission may be granted to any person who intends to use a patented invention (utility model) or if there are grounds and in compliance with the requirements of Art. 30 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models". The interested person applies to the central executive body, which is responsible for deciding on the use of the object, with a reasoned petition for permission of the Cabinet of Ministers of Ukraine, which indicates the name of the object, the number of the patent, information about its owner, their address (or location), as well as information on the unjustified refusal of this owner to issue a license to use the object. Attached to the petition are substantiation of the need to use the facility in the public interests, indicating the specific circumstances of the case; feasibility study of expediency, possibility, and conditions of use of the object, the amount of compensation to the owner of the corresponding patent (certificate).

However, there is special legal regulation in the field of compulsory licensing of inventions and utility models in the field of health care. In particular, in accordance with Part 14 of Art. 9 of the Law of Ukraine "On Medicines" dated 04.04.1996, in order to ensure the health of the population during the registration of a medicinal product, the Cabinet of Ministers of Ukraine in accordance with the law may allow the usage of a patented invention (utility model) relating to such a medicinal product to a person without the consent of the patent owner [22]. In pursuance of this norm, the Cabinet of Ministers of Ukraine adopted Resolution of 4.12.2013 №877, which approved the Procedure for granting permission to use a patented invention (utility model) relating to a medicinal product by the Cabinet of Ministers of Ukraine. This Procedure is a special normative-legal act that regulates the relations on granting compulsory licenses for the usage of inventions (utility models) for the purpose of public health protection, including combating HIV/AIDS and other socially dangerous diseases. According to the Procedure in question, it is not necessary to have an emergency in the field of health care. It is enough to refer to the aim – to ensure public health, including the fight against HIV/AIDS and other socially dangerous diseases. However, the question arises as to which diseases are considered socially dangerous and whether COVID-19 belongs to them. The Doha Declaration lists malaria tuberculosis and other epidemics, although it is not part of national legislation. The Law of Ukraine "On Protection of the Population against Infectious Diseases" [25] provides for tuberculosis, sexually transmitted diseases, AIDS, and leprosy among "socially dangerous infectious diseases".

Also, the issue of the situation in the field of public health, which necessitates a compulsory license, remains unresolved. Based on the provisions of the Procedure, such a circumstance occurs when "the patent owner cannot satisfy the need for the respective medicinal

product with the forces and capacities normally used for the production of such medicinal product" when the supply of a particular drug does not meet the demand. Then what to do if the supply is sufficient, but the drugs are sold at a price too high for the population, when consumers can not afford to buy such a drug? After all, the Procedure does not define any other arguments, including the price of a medicinal product, as a basis for issuing a compulsory license [27-31].

In addition, unlike the patent law, the Decree still requires the applicant to provide documentary evidence of the unjustified refusal of the patent owner to issue a license to use the patented invention (utility model) at the request of the applicant [31-36]. Compliance with such a waiver requirement is quite problematic, as the right holder will clearly be uninterested in granting such a license. Effective, in this case, is not obtaining permission but warning (notification) of the right holder about the intention to obtain a license, and if the right holder within a certain time (for example, 10 days) does not provide such a license, the user may apply to the competent authority for compulsory licenses [37].

The situation with the initiator of the authorization for the use of a patented invention (utility model) concerning a medicinal product is also unclear. Currently, it is an interested business entity that applies to the Ministry of Health of Ukraine with appropriate proposals, i.e. the function of initiating the issuance of a license is entrusted to the interested business entity. At the same time, it is the applicant who substantiates the need to use a patented invention (utility model) indicating the specific circumstances of the merits of the case and the required term of the patent use permit. However, there may be a situation where the applicant is a commercially interested producer who will act in their own interests and not in the interests of the population. Therefore, the sole initiator of a compulsory license should be the state, represented by the relevant authority, which is responsible for making the appropriate decision. Only such an approach will avoid direct conflicts of interest when the mechanism is launched either by a manufacturer interested in obtaining a permit or by an institution or organization affiliated with it [38].

However, Ukraine is still taking some steps in this direction. Thus, the Verkhovna Rada Committee on Health of the Nation has prepared a bill "on compulsory licensing of drugs to combat coronavirus infection", which will be considered in the near future [26]. Even if such a bill is not passed, it is sufficient to have existing legislation in this area on compulsory licensing of medicines, personal protective equipment, cleaning systems, treatment of diseases, and air disinfection. It means that Ukrainian pharmaceutical manufacturers will be able to produce personal protective equipment, cleaning systems, treatment of diseases, and air disinfection, which are patented by other pharmaceutical companies [39].

It should be noted that we should not forget what to expect after the COVID-19 pandemic when pharmaceutical manufacturers will feel the relief of social pressure on their patents. Thus, the position of the WHO and the European Medical Association (EMA) makes it clear that all data obtained in the course of such research cannot be monopolized by intellectual property instruments, neither as objects of patenting for a new scope/new purpose nor in the exclusivity of drug dossier data. Despite the unequivocal position of the WHO, the EMA, and the public, after the end of the COVID-19 pandemic, pharmaceutical companies will have their hands untied to monopolize medicines in Ukraine. This means that both the Ukrainian patient and the manufacturer may be affected.

Conclusion

The need for compulsory licensing is determined by the public interest and is an important legal institution. The success of the usage of the compulsory licensing mechanism as a tool to expand access to new and vital technologies (especially in the medical and pharmacological spheres) and other innovations for society is quite effective and depends on clear legal regulation at the level of national legislation and political will in the state. Compulsory licensing is an effective tool for balancing the public interests and patent owners and is designed to prevent the rights of patent owners from jeopardizing public health or being an obstacle to combating socially dangerous diseases. It is obvious that the existing legislation is extremely important but still needs further refinement and improvement.

Compulsory licensing in Ukraine mediates the granting of property patent rights to inventions and utility models. The importance of the relevant legal regulation is preconditioned by the fact that the issuance of a compulsory license takes place without the consent of the patent owner, but in cases specified by law, that is why the procedure for such licensing should be clearly regulated and should reflect a certain balance of interests of both patent owners and the user. The terms of the compulsory licensing are not based on the mutual consent of the licensor and the licensee but are determined by the competent state body. In the future, the state body may revoke the compulsory license if the circumstances that led to its issuance cease to exist. Compulsory licensing is a mechanism that obliges the patent owner to grant a license to another party in the public interest. Finally, it should be noted that today the only area that has special legal regulation on the granting of compulsory licenses for patent law is the field of health care.

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