The International Legal Problems of Ensuring the Availability of Medications in Conditions of the COVID-19

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Authors’ contributions

This work was carried out in collaboration among all authors. Author OB, as the ideological leader of the research, formed the structure of the article, systematized and generalized the information and results of the research, researched problems and perspectives of compulsory licensing of pharmaceutical products and wrote the first draft of the manuscript. Authors NM and OS researched patent protection as one of the mechanisms for ensuring the availability of medications in Ukraine and other countries. Author YA performed the analysis of the practice of the European Court and European legislation on parallel imports of medications and managed the literature searches. Author OO researched issues of Parallel Imports Procedure as one of the Mechanisms for Protecting Patients’ Rights to Affordable Drugs and also researched international acts and agreements on the legal protection of pharmaceuticals. All authors read and approved the final manuscript.

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ABSTRACT

In the context of the COVID-19 coronavirus pandemic, the risks of individual pharmaceutical market players or groups of players taking measures to supply medications that may lead to an economically unjustified increase in drug prices or artificially create a shortage of products are increasing worldwide.

Aims: Finding the best way to protecting intellectual property rights for medications in conditions of the COVID-19 coronavirus pandemic.

Methods: The methodological basis of the study was formed by an integral and coordinated system of scientific methods that contributed to the study of such a complex socio-legal phenomenon as the availability of medicinal products in conditions of the COVID-19 coronavirus pandemic. At the same time, a synergistic approach was applied, which combined the special research methods of various branches of law, pharmaceutical science and practice.

Results: The article reveals and identifies the distinctive features of using patent protection measures and parallel imports in the drug markets of various countries of the world and the impact of the TRIPS Agreement on the availability of medications for the public in conditions of the COVID-19.

Conclusion: For many countries, including Ukraine, the introduction of parallel imports can be efficient in the short term. Allowing parallel imports of medications has significantly fewer negative consequences for the copyright holder, since the improper quality of the products, in which the invention is used without the use of a trademark, most often does not affect the business reputation of the patent owner. Nevertheless, the chosen model of permitting the use of parallel imports to ensure the availability of medications in Ukraine remains a topical and controversial issue that requires a lot of professional discussion. Legislators should be very careful and cautious about the development and implementation of the institution of parallel imports of medications to Ukraine paying attention to the development of a whole system of quality and transparency control for procedures related to parallel imports to this country.

Keywords: Pharmaceutical market; COVID-19; medications; patent protection; parallel imports; medical law.

1. INTRODUCTION

The relevance of the issues of developing competition in the pharmaceutical markets is primarily connected with their dynamic unfolding and direct impact on the living conditions and health of the population of the respective countries. The massive spread of a virus that is dangerous to human health has become a new test for almost all countries of the world. ICTV announced "severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)" as the name of the new virus on 11 February 2020. This virus causes a disease in humans called "coronavirus disease (COVID-19)" [1]. WHO officially referring to the virus as "the virus responsible for COVID-19" or "the COVID-19 virus" when communicating with the public. The massive spread of this virus is confirmed by official WHO data. As of 10 August 2020, the pandemic had reported 19,877,261 cases in over 188 countries and territories; 731,570 people died [2]. In the context of the COVID-19 coronavirus pandemic, the risks of individual pharmaceutical market players or groups of players taking measures to supply medications that may lead to an economically unjustified increase in drug prices or artificially create a shortage of products are increasing worldwide.

For the quarantine period, in order to ensure price stability and availability of medicines and personal protective equipment, the Government of Ukraine temporarily resumed state regulation of prices for goods of significant social importance and anti-epidemiological goods by declaring changes in retail prices in case of their increase. In particular, drugs such as Paracetamol, Azithromycin, Amoxicillin and beta-lactamase inhibitor, Ampicillin, Amoxicillin, Ceftriaxone, Moxifloxacin, as well as some antiseptics (for example, Chlorhexidine, Ethanol, Chlorosilenols) and personal protective equipment fell under state regulation [3]. Unfortunately, this decision caused both positive and negative effects, consumer agiotage. In the first weeks of quarantine, as a result of the transformation of purchases from pharmacies, almost all tools and remedies disappeared, and
unscrupulous entrepreneurs sold them at simple inflated prices. In addition, in the conditions of a sharp shortage of such goods, their illegal export from the country has become more frequent in Ukraine. So, for example, in March 2020, at the Ukrainian-Polish border, border guards found 10,653 medical masks that a citizen of Ukraine wanted to illegally take out of the country [4], inspectors of the Dula border service of the Mukachevo detachment on March 4, 2020 prevented the illegal movement of more than 3 thousand medical masks from Ukraine to Romania [5]. Public authorities recommend that business entities refrain from any action that may bear signs of a violation of economic competition laws and may lead to an increase in prices for pharmaceutical products.

The pharmaceutical industry is a complex element in the structure of the countries' economies that combines market mechanisms (interaction between consumers (patients), intermediaries (wholesale and retail ones), manufacturers of medications and health authorities) with the performance of a social function in the field of providing the population with medications thus implementing the right of each citizen to receive medical care.

Quite recently, pharmaceutical markets in many countries have been considered competitive because they have a large number of players. However, the growing volume of those markets, high rates of drug price increases, the shortages of certain products, the need for efficient budget spending and the social significance of drug markets for the state and the society as a whole have forced antitrust authorities to conduct more thorough research and change their views on the market concentration. After all, the availability of medical care for the population directly depends on the degree of competition in the pharmaceutical markets. Those studies have shown that the pharmaceutical industry in Eastern Europe is largely embraced by multinational companies, with mixed consequences. Business entities that are part of multinational companies are less responsive to the negative challenges of the environment. The following is common to all pharmaceutical multinationals operating in the markets of Eastern Europe and, in particular, in Ukraine: strong positions in most strategic global pharmaceutical markets; global integration, which makes it possible not to take into account national characteristics; the implementation of a flexible public procurement strategy; global production structure; global research and development organization; global marketing organization that ensures a strategic focus on the interests/needs of customers. Thus, it can be predicted that the danger of global pandemics, the COVID-19 in particular, will lead to an intensification of mergers/acquisitions (creation of alliances) in the global pharmaceutical industry, which in turn will lead to total oligopolization of pharmaceutical markets.

When forming an efficient state policy in Ukraine in the field of circulation of medications and pharmaceutical activities, it is important not only to take into account the national characteristics, the state of economic development, priorities in the social sphere, but also to use the positive experience of various countries, the study of which has actually determined the relevance of the present research.

Not only legal acts, practical experience of governments and leading pharmaceutical companies of different countries, but also such an important resource as ideas, conclusions set forth in national and international scientific works of leading scientists and practitioners become important and valuable for this purpose. In particular, the works of J. Lexchin [6], who studied the Canadian experience in protecting the right of citizens to access medical drugs, S. Correa [7], who revealed the features of integrating public health concerns into patent legislation in developing countries, A. Yevkov [8], who highlighted the current problem of legal regulation of parallel imports of goods containing intellectual property, and the exhaustion of exclusive rights in the legislation of Ukraine, and many other works were useful for our study.

2. METHODS

The methodological basis of the study was formed by an integral and coordinated system of scientific methods that contributed to the study of such a complex socio-legal phenomenon as the availability of medicinal products. At the same time, a synergistic approach was applied, which combined the research methods of various branches of law and pharmaceutical science.

The use of the formal legal method contributed to the analysis of regulatory legal acts in the field of patent protection of the pharmaceutical industry. The methods of comparative legal and
generalization was used for analyzing approaches to the functioning of the pharmaceutical market in different countries of the world (in particular South Korea, Mexico, Thailand, USA, Brazil, Ecuador, India, Finland, Denmark, Sweden, Germany, Norway, Holland, UK, Japan, Australia, Canada, USA).

Methods of descriptive and abstract modeling and scientific generalization, as well as the prognostic method were used to form conclusions, recommendations and proposals to substantiate the directions of optimization of state policy to ensure the availability of medicines for the population.

The theoretical basis of the study consisted of scientific and methodological works of Ukrainian and foreign experts in the field of pharmaceuticals, intellectual law, international law, related to the topic of our study.

The legal basis of the study is the legislation of Ukraine, which regulates the activities of economic entities in the field of manufacture and circulation of medicines, patent rights, legislation of foreign countries, international legal acts of World Trade Organization, World Health Organization, World Intellectual Property Organization, and also solutions European Court of Human Rights.

3. RESULTS AND DISCUSSION

3.1 Patent Protection as the One of the Mechanisms for Ensuring the Availability of Medications

The experience of industrialized countries shows that intellectual property protection has been and remains one of the most powerful tools for economic development, increasing export opportunities and spreading new technologies. For the global pharmaceutical industry, the economic aspects of protecting intellectual property rights to inventions and trademarks are of particular importance. Manufacturers of original pharmaceutical brands protect their exclusive rights in various ways, primarily through the use of industrial property law tools.

Since 1970, spending on research and development (hereinafter referred to as the R&D) in the pharmaceutical sector has been steadily increasing, doubling approximately every five years. Starting in 1980, leading pharmaceutical companies have continuously increased the share of sales revenue that is spent on funding research and development, which nowadays reaches 15% on average (in 1981, it was 9.5%), while in the United States that figure is even 20%. At the same time, for the U.S. industry as a whole, this figure is 3% (in the computer industry and electronics, it is 8% and 6%, respectively) [9, p.158]. There is no doubt that the risk of the COVID-19 pandemic has led to an increase in these indicators by an average of 3 to 5%.

Currently, there is a tendency to enhance the efficiency of using exclusive patent protection regimes on a global scale. This applies primarily to the pharmaceutical sector, for which, due to the huge and growing costs of creating new drugs and the extremely high associated risks, legal protection of inventions is particularly important. We can see how the largest manufacturers, with the support of their own governments, compete in the speed of developing and testing COVID-19 vaccines. At the same time, there is an ongoing debate about the excessive rigidity of patent legislation in the field of drug circulation, which, in the opinion of many, restricts access to the latest pharmacotherapy technologies for the population of poor countries and contributes to the monopolization of the market and price increases for the purpose of obtaining super-profits. Consequently, the problem of pharmaceutical patent protection is quite relevant and has a number of closely related economic, socio-political and ethical aspects [10, p. 176].

Patent protection is the most important element of the intellectual property protection system. The basis of its application and use is the limited period (for example, in Ukraine and India it is 20 years) of exclusive rights to manufacture, use and sales to the public of a new substance, technology, etc., which makes it possible, during that period, to reward inventors (individuals or organizations) for the risks they agree to run at the stage of the R&D, and to reimburse their costs for that activity. A patent can be considered something like a symbol of inventive activity, and regarded as an incentive for progress. The public importance of the patent protection for pharmaceutical products (including vaccines) is well known. In particular, it should be noted that:

- More than 90% of the medications currently available in the market are the result of applied scientific research that has become possible only in the presence of such an incentive as the exclusive right
of market sale, which is ensured through patent protection;

- Patent protection establishes the necessary balance between the natural desire of inventors to compensate for costs and the needs of society for new efficient medications;
- Efficient patent protection provides manufacturers with the time they need to train specialists in the proper use of new medications and treatment methods.

In the field of patent protection, there are regional agreements and conventions at play. Of particular importance to the global pharmaceutical industry is the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as the TRIPS Agreement), which was adopted during the Uruguay Round of multilateral trade negotiations (in 1986-1993) within the framework of the World Trade Organization and entered into force on January 1, 1995 [11, p. 37]. The purpose of the Agreement was to harmonize the national legislation on intellectual property protection and to provide the standards of intellectual property protection that need to be incorporated into the national patent law.

At the same time, the TRIPS Agreement provokes the most contradictory assessments by specialists, because, while ensuring the protection of intellectual property rights, it also provides for the need to ensure the affordability of medical treatment for patients. From the point of view of some researchers, the TRIPS Agreement is based on the concept of intellectual property protection, according to which private interests dominate over public ones [12, p. 56].

On the one hand, the enormous cost of developing new drugs is an argument for supporting compliance with intellectual property and patent protection laws in the pharmaceutical sector, as bringing the invention in the field of pharmaceuticals and biotechnology to the stage of its practical implementation is a long, expensive and risky process. An efficient system of intellectual property protection, which provides periods of exclusive rights in the market, is therefore crucial for the knowledge-intensive pharmaceutical industry. During those periods, it is possible to recoup the cost of the R&D (experts believe that the costs are recouped in 18 years from the date of filing the application for the invention). On the other hand, the following arguments are put forward to support and defend the practice of non-compliance with intellectual property laws in the pharmaceutical sector:

- High prices for pharmacological products are mandatory at the time of their introduction onto the market. Indeed, patented drugs and formulas are expensive and not affordable to everyone, although in industrialized countries that problem is solved through compensation and insurance schemes. It is appropriate to note that if in industrialized countries the share of manufacturers in the structure of the final consumer price is 50 to 60%, in developing countries that figure is only 20%, while the remainder is import taxes, duties, distributors' income and retail surcharges [13, p. 21].
- There is a possibility that patent protection will lead to the stagnation of the national pharmaceutical industry. This risk may manifest itself in cases where there are pharmaceutical monopolies in the country, a closed pharmaceutical market. However, the experience of many countries shows that the introduction of a modern and efficient system of patent protection of pharmaceutical products not only ensures the rights of foreign manufacturers, but also contributes to the rise of the national pharmaceutical production. Firstly, the adoption of such a system contributes to the commercialization of inventions, the modernization of existing industries, the creation of modern production, trade and service infrastructure providing convenient and rapid access to the latest achievements in the field of pharmaceutical technologies. As a result, the outflow of national workforce is slowed down, and the overall level of knowledge in the pharmaceutical community is increased. Secondly, patent protection increases the country's credibility and promotes its recognition as a reliable supplier. The lack of adequate patent protection hinders the export of pharmaceutical products, as buyers from other countries will always be afraid to purchase pirated copies of drugs. At best, such an exporting country will be seen as a supplier of cheap low-quality products.

The positive impact of international patent protection standards on the development of the pharmaceutical industry can be illustrated by a
number of examples. In South Korea, patent protection introduced in the pharmaceutical industry in the late 1980s has led to an increased investment, especially by local private companies, in the R&D. The share of domestic manufacturers in the South Korean market increased up to 87.3% in 1990. In Mexico, since the enactment of the patent protection legislation in 1991, the R&D investment in the pharmaceutical sector has tripled. The point of view of the U.S. pharmaceutical companies, who until 1991 had not wanted to transfer the latest technologies even to their Mexican subsidiaries that were in their full ownership, also changed. The progress of the Japanese pharmaceutical industry, which is now one of the world market leaders, had been constrained before the adoption of legislation on the protection of pharmaceutical patents in 1976. That eventually led to the situation where in the mid-1970s Japan paid foreign companies for drug licenses 3 times more than it earned itself, then since 1986 the country has become a net exporter of such technologies [10, p. 220].

In this context, the TRIPS Agreement has made more relevant the problem that goes beyond the scope of the World Trade Organization (hereinafter referred to as the WTO). The problem lies in that whether the existing public mechanisms embodied in the system of protection of intellectual property rights provide the most efficient way of creating optimal conditions for obtaining and disseminating new knowledge and the R&D results. Society faces two challenges, i.e. creation and invention, on the one hand, and dissemination and implementation, on the other. An ideal system of intellectual property protection should provide for the use of two tools: the first tool would provide optimal incentives for acquiring new knowledge and reimbursing significant fixed costs associated with that process, while the second one would provide the possibility of accessibility and production to maximize the benefits of the dissemination and implementation of that knowledge. In this context, setting the duration of patent protection is the most complex and controversial issue.

There are two main groups of medications available in the pharmaceutical markets, viz. original medications and generic ones. Creating an original (innovative) medication is quite a long and expensive process. In most cases, it takes more than ten years to develop a new drug from

the new molecule research stage to the registration one, while the cost of creating such a drug runs into millions of U.S. dollars. Only competitive innovative drugs can overcome the long journey from the moment of creating a new molecule until introducing the drug onto the pharmaceutical market. The basis for future success in pharmaceutical markets is the demand for the drug, and only time can show how competitive it will be [14, p. 52].

Generic drugs are the drugs that are reproductions of original drugs, whose active pharmaceutical ingredients are no longer under patent protection due to the protection period expiration. According to the existing requirements, the introduction of generics onto the market does not require significant preclinical and clinical tests (as compared with the original drugs), which significantly reduces their cost. In the vast majority of cases, a proven pharmaceutical, biological, and therapeutic equivalence of those drugs is a prerequisite for recognizing the identity of the generic and the original medication. The main requirements for generic drugs nowadays are their compliance with the quality, efficacy and safety standards of the original medications.

Manufacturers of original pharmaceutical brands defend their exclusive rights in various ways, primarily through patent protection. The implementation of patent protection for a particular molecule being the basis of a medicinal substance provides for a prohibition of that molecule’s reproduction for a period of time, the duration of which varies from country to country. In the EU countries, that period is 10 to 15 years, while in Russia and Ukraine it is 20 years. Even in economically developed countries, the use of generics is encouraged by the state on condition of the mandatory observance of patent rights of manufacturers of original medications. In economic terms, generics will always be more acceptable than the original drugs, as they do not require huge financial costs for their creation and further research of their properties, as well as they are more affordable to the general population due to their lower cost compared to the original drugs [10, p. 22]. The use of high-quality and, as a rule, cheaper than the original medications generic drugs makes it possible, on the one hand, to reduce significantly government spending on medical treatment, and on the other, to maintain a high level and quality of that treatment.
It is no secret that companies focused on manufacturing original products need the longest possible protection time for their produce in order to recoup their expenses, reinvest funds, i.e. to support the further unfolding of their innovative developments. Generic drugs companies, whose number and influence have grown significantly in recent years, are interested in reducing that time, which benefits both the companies themselves and the healthcare system, as it helps saturate the market with more affordable medications.

The TRIPS Agreement envisages that the WTO members must ensure the patent protection of all inventions in all fields of science and technology for a period of at least 20 years [11]. However, as the Special Rapporteur on Human Rights Anand Grover pointed out at the UN General Assembly, the said Agreement differs from the Paris Convention of 1883 because it does not take into account the diversity of needs of various countries. For example, the Paris Convention and the follow-up agreements required only strict adherence to the principles of non-discrimination, with the national regimes and priorities taken account of. Countries were given a sufficient degree of flexibility in their actions to adapt the adopted intellectual property protection regimes in accordance with their socio-economic needs and goals. It was also permitted to withdraw certain sectors of the economy, including the pharmaceutical industry, from the patent sphere and to determine the period of protection of the relevant copyrights. That is why the number of countries that signed the 1883 Paris Convention for the Protection of Industrial Property is more than that of the WTO member (As of March 2, 2013, there are 175 countries that are parties to the Paris Convention versus 159 countries that are the WTO members). That being the case, in the context of ensuring the access to medical treatment for the public, it is the TRIPS Agreement that is controversial, in particular, in terms of patenting, including pharmaceutical products, given that disputes related to the protection of intellectual property rights must be considered by the bodies authorized to settle such disputes [15, p. 56].

At the same time, since the beginning of the Uruguay Round on the conclusion of the TRIPS Agreement in 1986, the participating countries were given the possibility to determine independently the validity of patents in their territory. As a result, nearly 50 countries decided not to issue patents for pharmaceutical products at all [16, p. 5]. In addition, some countries did not accept for consideration applications for technological processes of pharmaceutical production [17].

It should be noted that the Indian pharmaceutical industry actually emerged and developed as it is in the special regime of patent protection for pharmaceutical products before 2005. Thus, the Indian Patent Act of 1970 abolished patents for pharmaceutical products and ensured an appropriate legal regime that allowed Indian pharmaceutical companies to manufacture generic copies of patented drugs at minimal cost. That strategic choice enabled India not only to meet its own pharmaceutical needs, but also turned the country's pharmaceutical industry into a huge supplier of low-cost generic drugs [18].

However, the TRIPS Agreement limited the powers of the WTO members for using their national law by introducing mandatory standard requirements for the protection of intellectual property rights. The ratification of that Agreement was a prerequisite for Ukraine's accession to the WTO. Nevertheless, as experts point out, it is necessary to recognize the fact that the unification of minimum standards for the protection of intellectual property rights within the WTO framework has a direct impact on the availability of medications in member states. This is primarily conditioned by the identical approach to the objects that can be protected as inventions, in terms of granting them the scope of exclusive rights, as well as to the requirements for the protection of "undisclosed" data related to pharmaceutical products [19]. It is no coincidence that according to the independent international medical humanitarian organization Médecins Sans Frontières (Doctors Without Borders), in the countries, in whose markets medications are protected by patents and where there are no generics, the cost of medical treatment is significantly higher than in the countries where drugs are not protected by patents or where a patent owner permits competition. In addition, compared to developed countries, the benefits of patenting pharmaceuticals in the least developed and developing countries are not as obvious. The latter are forced to import medications and purchase the respective licenses for the use of patented inventions, because their economic condition does not make it possible for them to develop the latest technologies. As a result, there is an outflow of funds from those countries to developed ones, where the main volume of production and scientific capacities is located.
and, in fact, where most of the patent applications, including in the pharmaceutical industry, originate [20,21].

Perhaps that is why there is now a view that the TRIPS Agreement was created and functions only in the interests of high-income countries having economies based on intellectual values. However, as some researchers point out, due to the existence of exclusive property rights, a patent owner can, within the period prescribed by law, limit the ability of competitors to use the respective innovation. Thus, the mechanism of return of the funds invested in innovations is implemented for the purpose of their further attraction for investing in new developments. At the same time, according to the WHO, the development of drugs for diseases common to 90% of the world's population costs only 10% of the annual expenditure for health care research [22]. That being the case, the U.S. pharmaceutical industry, for example, spends more money on marketing than on the development of new products.

From the point of view of the developers of the above-mentioned Agreement, the document contains a number of provisions that allow the participating countries to take appropriate measures for the purpose of improving health care, in particular, for increasing the availability of medications for the public. They are called the "flexible provisions" of the Agreement. In addition, the Doha Declaration on the TRIPS Agreement and Public Health [23] notes the importance of implementing and interpreting the TRIPS Agreement in the most favourable way for the protection of public health: by making existing medications available to the population and creating conditions for the production of new ones. The Declaration also states that the provisions of that Agreement do not and should not conflict with the right of the member states to take appropriate measures to protect public health.

The experience of the WTO member states also testifies to the fact that developed countries can freely interpret certain "flexible provisions" of the TRIPS Agreement. For example, Thailand came under pressure from the United States after trying to apply the mechanism for compulsory licensing of pharmaceutical products. In 2006-2007, Thailand issued compulsory licenses for medications to treat HIV/AIDS and cardiovascular disease. However, as early as 2007, the country was included in the priority checklist of the "Special Report 301" by the US Trade Mission. The position of the European Commission was also not to approve measures applied by Thailand [16].

The WTO cooperates with a number of international organizations, including the WHO. The WTO and the WHO work together to address various trade and public health issues where the activities of those organizations overlap. There is no formal cooperation agreement between the WTO and the WHO, but the WHO has an observer status on the WTO Committee on Sanitary and Phytosanitary Measures and on the WTO Technical Barriers to Trade Committee. On top of that, the WHO has an ad hoc observer status on the TRIPS Council and on the General Agreement on Tariffs and Trade (hereinafter referred to as the "GATT") Council. The secretariats of both organizations work closely together in the field of sanitary and phytosanitary measures, as well as food safety. They pay special attention to the issue of the availability of necessary medications for the public in the context of the TRIPS Agreement and the attempts on the part of the developed countries to strengthen further the protection of intellectual property rights.

Such cooperation is necessary for the WTO to address global health care issues. The WTO also works closely together with the World Intellectual Property Organization, which makes it possible to assess more objectively the balance between health care and intellectual property. For example, the UN drew attention to the so-called lifetime renewal of patents for pharmaceutical companies. This refers to the practice of extending patent protection for pharmaceuticals by making minor changes to patents, which delays the production of generic drugs.

So nowadays, the representatives of the developed countries that contributed to the development of the current TRIPS Agreement recognize that the introduction of the patent protection regime for medications in low- and middle-income countries is likely to be an obstacle to further increasing the affordability of low-cost generics for their populations. However, in their opinion, countries have the possibility to establish independently criteria for the patentability of inventions by using their domestic legislation. Thus, Article 27 of the TRIPS Agreement defines three mandatory criteria for the patentability of inventions, viz. "novelty", "level of invention" and "industrial applicability".
There is no definition of the criteria or the procedure for their interpretation. However, the footnote to that article allows participating countries to equate the term "inventive step" adopted in most European countries with the criterion "non-obvious", which is standard in the U.S. patent system. That is, member states may refuse to extend patent protection in cases where minor changes to patents are made on the grounds that the latter do not meet the conditions of novelty, inventive level or industrial applicability [22,23]. For example, Section 3 (d) of Chapter II of the Indian Patent Act and Patent Rules provide for extend patent protection on the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or on the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant [24]. In addition, the report of the European Commission for 2000-2007 notes a decrease in the number of new medicinal forms with an increase in the number of patent applications filed. Most of them (87%) were filed for so-called secondary patents.

It should be noted that this situation, viz. extending the validity of patents through minor modifications to the drug, is usually typical for the developed countries, in particular, the United States and France [7]. The fact that such an application is granted means the extension of the patent protection for another 20 years and non-admission to the market of generics, whose prices are much lower than those of the original drugs. The developing countries in turn warn against such practices. Some of those countries have begun taking certain measures to prevent issuing patents for new medicinal forms and indications for their use.

In order to increase the capacity of a national pharmaceutical industry to meet the needs of public health, the so-called compulsory licensing is applied. The principle of compulsory licensing is enshrined in Article 31 of the TRIPS Agreement that provides for the possibility of using patented products without the permission of the patent owner, subject to the payment to the latter of an adequate monetary compensation. That being the case, the TRIPS Agreement does not provide for the limitation of the grounds for applying compulsory licensing. Accordingly, each country has the right to develop independently its own compulsory licensing regime that would permit, under certain conditions or in order to achieve strategic goals, to manufacture or import generic versions of patented drugs.

Compulsory licensing was used by the governments of some countries, including India (for example, Nexavar is the first and only drug which has received a compulsory licence from the Indian Patent Office), Brazil, Ecuador and Thailand, both for the production of ready-made medications and for their importation from other countries. There are cases when the mere threat of using the compulsory licensing mechanism led to a significant reduction in prices for ready-made drugs. Many countries, including developed ones, the United States in particular, issue compulsory licenses for various reasons, such as overcoming the consequences of anti-competitive practices [25].

The Doha Declaration clarifies that each country shall independently determine the grounds for applying the compulsory licensing procedure. That is, an emergency does not have to be the reason for applying the compulsory licensing procedure. Moreover, countries themselves shall determine whether the circumstances are extraordinary or not.

3.2 Parallel Imports Procedure as the One of the Mechanisms for Protecting Patients’ Rights to Affordable Drugs

In addition, the use of the parallel imports procedure can be considered one of the mechanisms for protecting patients' rights to affordable drugs and at the same time for expanding economic activity in the pharmaceutical market. That procedure is used if the price of the drug made by a particular manufacturer differs from country to country. In this case, it is better to import the drugs in question from countries where they are cheaper. The Doha Declaration recognizes the right of each country to apply the parallel imports procedure. In order to implement parallel imports, it is necessary to develop a special legal mechanism for both registration and importation procedures. Also, in our opinion, in the event of violation of the legislation on economic competition, compulsory licensing should be applied simultaneously with the parallel imports procedure. Consequently, the following mechanisms can nowadays be identified within the framework of the TRIPS Agreement to
The above to the forecasts of retail chains, the adoption of the copyright holders of the products. According not only by hand the company that legally purchased those products, the legal rights to the parallel imports. As of today, the Verkhovna Rada (i.e. the Ukrainian parliament) of Ukraine is considering Draft No. 2255 of the Law of Ukraine “On Amendments to Several laws have been submitted to the Verkhovna Rada of Ukraine that would permit parallel imports of medications, but, as experts note, there is a lot of controversy over whether falsified, low-quality drugs will flow into Ukraine in case parallel imports are legalized. Besides, the relevant statutory documents do not provide for proper quality control of imported drugs. At the same time, the draft laws submitted to the Verkhovna Rada of Ukraine propose to solve the problems of the modern pharmaceutical market of Ukraine, one of which is the following: the artificial monopoly of protection documents (patents) in the market of medications is terminated, where owners of a patent for a medication seek a secondary patent after the expiration thereof, but not through a change in the medication appearance or its dosage. The monopoly on the sale of such a drug due to the patent rights abuse can last for decades.

For the pharmaceutical market of Ukraine, the issue of parallel imports of medications is one of the most controversial. This issue is now widely discussed both by the pharmaceutical community and by all patients who go to pharmacies every day to buy certain drugs. Several bills have been submitted to the Verkhovna Rada of Ukraine that would permit parallel imports of medications, but, as experts note, there is a lot of controversy over whether falsified, low-quality drugs will flow into Ukraine in case parallel imports are legalized. Besides, the relevant statutory documents do not provide for proper quality control of imported drugs. At the same time, the draft laws submitted to the Verkhovna Rada of Ukraine propose to solve the problems of the modern pharmaceutical market of Ukraine, one of which is the following: the artificial monopoly of protection documents (patents) in the market of medications is terminated, where owners of a patent for a medication seek a secondary patent after the expiration thereof, but not through a change in the medication appearance or its dosage. The monopoly on the sale of such a drug due to the patent rights abuse can last for decades.

Secondly, the authors of the draft laws propose separating the procedures for registering medications and obtaining patent rights. This will allow the manufacturers, who do not have a patent for a particular drug, to begin preparatory procedures for its registration during the term of the patent, so that immediately after the document expires they could produce and sell the drug in question.

And thirdly, parallel imports of medications are introduced, i.e. the imports of drugs that are already registered in Ukraine but that are imported without a special permit from the manufacturer.

It is worth noting that the parallel imports regime functions in many countries of the world. In Europe, the parallel imports mechanism has been in place for twenty years, which significantly contributes to lower drug prices. It is reducing prices, creating a competitive market, and speeding up the passage of goods through customs that the new statutory document should
be aimed at, but with clear rules of the game and responsibility for this type of activity. For example, the annual volume of parallel imports in Poland has reached more than PLN 401 million. The number of pharmaceutical products has grown significantly in recent years there. At the same time, Poland has developed clear rules that help ensure that high-quality medications are imported into the country. That is, we have someone to take as an example before parallel imports cross Ukrainian borders. The key factors here should be the control over the importation of drugs, as well as the patients themselves and what medications and at what price they will buy in domestic pharmacies as early as in the near future.

As experts note, the expansion of the price affordability and physical availability of medications for the EU countries’ population is largely due to parallel imports that function between the countries of the European Union only and are based on the principle of free movement of goods. According to the European Court of Justice, a pharmaceutical company that manufactures innovative medications in the EU territory and restricts parallel exports by refusing to satisfy ordinary orders made by wholesalers thereby abuses its dominant position and violates the principles of competition that are in force in the EU. Parallel trade creates conditions for patient consumers to be able to purchase the same drugs at lower prices while being confident that the same standards of drug safety are maintained.

Parallel imports are another potentially useful mechanism under the Agreement on Trade-Related Aspects of Intellectual Property Rights [10] for increasing access to medications in developing countries. What is usually meant is the importation and resale of products that are patented in the importing country, legally advertised and sold in the exporting country. This step can be applied without the approval of the patent owner. This is usually done in cases where patented drugs are sold in the importing country at a higher price than in the exporting country. Potential cost savings when using parallel imports of vital drugs – which, in particular, Kenya resorted to for the purchase of some antiretroviral drugs – may be crucial for countries with limited resources [10,p.26,191;27].

Before enacting parallel imports, countries usually need to work out and adopt laws that directly permit them. After that, they will largely be protected from possible legal sanctions under Article 6 of the Agreement on Trade-Related Aspects of Intellectual Property Rights [11], which explicitly states that no provisions of that Agreement may be used against a WTO member country for allowing parallel imports carried out in accordance with the country's domestic laws.

Parallel trade is a mechanism that helps reduce prices in the European market. In various national markets, the share of medications coming through these channels ranges from 1.7% (Finland) to 16.5% (Denmark). Parallel imports are allowed and encouraged by the European Commission as a tool to support competition and reduce prices in the EU territory. However, the cost of such distribution is that for consumers the prices of those medications are ultimately not much lower than usual, i.e. a significant part of the added value is redistributed in favor of intermediaries. The reasons for this phenomenon are due to the fact that trade surcharges in Europe vary significantly. On the one hand, surcharges can be set by the state, on the other hand, they indirectly depend on the regulation of the number of pharmacies, as well as the rules that restrict the concentration or, conversely, contribute thereto in the wholesale and retail markets. In some countries, where this is permitted, manufacturers use direct supply schemes to deliver their products to retail chains in order to combat parallel trade. They also try to limit in a legitimate way the number of distributors they work with in the national markets [28].

In its decisions, the European Commission notes that drugs imported in parallel are generally cheaper than equivalent products; the former play an extremely important role in providing the market with medications at lower prices during the period of patent protection, when it is not yet possible for generics to enter the market.

Parallel trade in goods provides an additional source of their supply in the market. This is especially important from the consumer's point of view when it comes to branded and patented products. In cases where there are few alternatives in the market, parallel trade is the only source of competition. In addition, patients directly benefit from parallel trade in cases when they are forced to pay the full cost of a branded medication themselves or when the government reimbursement is only partial and expressed as a percentage of the full cost of that medication.
Many developed countries, such as Sweden, Germany, Norway, Denmark, the Netherlands and the United Kingdom, use a variety of mechanisms and incentives to support parallel trade. For example, in Sweden, Denmark and Norway, drug interchangeability at the pharmacy level applies not only to generics, but also to medications imported in parallel. In the United Kingdom, the reimbursement paid to a pharmacy is reduced if its sales of medications imported in parallel are lower than the corresponding percentage ratio. In Sweden, in particular, prices for the drugs imported in parallel are 10-15% lower than the prices for the corresponding medications [29,30].

Parallel imports are unconditionally allowed in some countries, unconditionally prohibited in other countries, while in still other countries their permission or prohibition made dependent upon a number of factors, such as the risk of misleading consumers about the quality of the products. This step is explained primarily by the fact that the low levels of production and technological development of the participating countries do not allow a significant portion of the citizens of those countries to meet most of their needs using domestic resources only. Such freedom of action is in line with the provisions of Article 6 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, which enshrines the right of a participating country to recognize a particular concept of the exhaustion of intellectual property rights.

Countries that allow parallel imports proceed from the following:

- from the interests of consumers who do not care who manufactures the product, as long as the quality of the product remains at the same level (Japan, Canada);
- the need to support the domestic market (Third World countries).

Allowing parallel imports is in the interests of consumers, since it prevents copyright holders from setting monopolistically high prices for their products and forces the copyright holders to indicate honestly the country of origin. For example, parallel imports are allowed in Japan, because it does not matter to the consumer where the products are manufactured if their quality corresponds to that of the products sold by the trademark owner in Japan [10, p. 195;30]. Those provisions were subsequently enshrined in statutory documents.

Parallel imports are closely related to the concept of "exhaustion of intellectual property rights". The principle of exhaustion of exclusive rights to intellectual property objects lies in limiting the ability of the copyright holder to use their rights to prevent further circulation of products containing the relevant protected objects after the latter's lawful putting into due circulation. This principle is embodied in the legislation of many countries, including Ukraine (in particular, in Part 7 of Article 15 of the Law of Ukraine "On Copyright and Related Rights", in Part 6 of Article 16 of the Law of Ukraine "On the Protection of Rights to Trademarks for Goods and Services", etc.) [8, p.141]. From the point of view of the territorial aspect of the application of the principle of exhaustion, three models can be distinguished: national exhaustion of rights, regional exhaustion of rights, and international one. If the exclusive rights of the copyright holder granted in a particular country are exhausted only in respect of those products that were put into circulation in the territory of that country, we are talking about the national model of exhaustion. That said, the copyright holder retains the possibility of controlling imports of the relevant products lawfully put into circulation in other countries. The regional model (existing, for example, in the EU) means the exhaustion of copyrights in respect of products put in circulation in the territory of any of the EU countries. That being the case, the principle of exhaustion of copyrights does not apply to goods put in circulation outside the EU. Finally, the international exhaustion means the application of that principle to products lawfully put in circulation in any country of the world [31,32, p. 70]. The possibility of legal justification of parallel imports appeared with the development of the concept of international (universal) exhaustion of intellectual property rights, which is used for the following purposes:

- restricting monopolistic activity;
- preventing the market division;
- ensuring the free circulation of goods in the market.

For example, in the United States, a flexible system for regulating parallel imports has taken shape. U.S. judicial practice is outwardly focused on protecting the interests of consumers, that is, if products imported in parallel do not technically conflict with the interests of U.S. consumers and do not mislead them about the quality of the products, if the imported products have no significant differences from the products manufactured in the United States, such imports
are allowed. For example, in June and July 2005, judges in a New York State district court issued injunctions against the companies called National Pet Supplies (Australia) and Abbeyvet Exports (UK) that distributed Novartis products (pet medications) over the Internet. The reason for issuing injunctions was that those drugs were sold to US citizens, among others, while they were intended for sale outside the United States, and therefore contained significant differences in the instructions for their use, dosage and labelling from the similar drugs manufactured by Novartis for the USA. The distributors disagreed with such an approach and stated that the websites offering those products had indications of the country, for which the drugs were intended. That, they said, precluded misleading consumers as to the quality and the origin of the products. However, those arguments were not accepted by the judges. Of course, when hearing that case, the rules of the U.S. drug law were taken into account including mandatory registration and the terms of drug sale to consumers.

Parallel imports may be prohibited or restricted by the state due to the following reasons [14]:

- based on the interests of copyright holders who incurred significant expenses for marketing a particular trademark or technology, while "shady" importers, without spending money on advertising and implementation, can afford to set dumping prices for their products (Spain, Russia);
- based on the interests of the national security, since, in particular, medications are of strategic importance to society, and, consequently, their quality must be guaranteed by the trademark in greater measure than for all other products.

Different countries have different conditions for the legal regulation of parallel imports of medications. In this case, it is necessary to take into account not only the intellectual property rights, but also the administrative norms related to the regulation of the circulation of medications in each specific country. Nevertheless, when discussing the issues of parallel imports, law-making and law enforcement bodies have to address issues related to the imports of medications. As already discussed above, the Novartis case ruling is based solely on the difference in the paper work requirements and the medication itself that is released onto the U.S. market. Similar restrictions apply to all developed countries: medications are subject to registration; medications must be accompanied by documentation of certain content; there are special requirements for the packaging of medications [33].

In order to ensure a single economic space, the EU member states not only adopted the concept of "regional exhaustion of intellectual property rights", but also developed a system for importing medications from one member state to another. In particular, a system of a simplified procedure for obtaining permission to import drugs under the "parallel imports procedure" was developed. That is, a company may not register a medication sold in an EU country, but only declare that it imports it under the parallel imports procedure from an EU country, subject to certain conditions. Previously, the condition for allowing the importation of drugs under the parallel imports procedure was the one that those drugs were of a "common origin". The "common origin" doctrine was developed by the EU Court of Justice, and is somewhat similar to the "economic link" doctrine described above: products are considered to be of a "common origin" if they are either manufactured by two companies belonging to the same group of persons, or under license agreements, according to which, the holder of the exclusive copyright is one and the same person [34].

However, on 1 April, 2004, when deliberating the case of Kohlpharma GmbH vs. Germany, the European Court of Justice ruled that drugs may be imported into a country under the "parallel imports" procedure if the following conditions are met: those drugs are legally put in circulation in one of the EU countries and are substantially similar to a local medication. In particular, that is the case if the medications contain the same active substance produced by the same manufacturer. Thus, by its decision, the court expanded the possibilities of parallel imports calling into question the "common origin" doctrine. That decision has not received an unequivocal support among legal experts in the European Union, and subsequent decisions by national courts do not follow that interpretation of parallel imports [35-36].

The issue of parallel imports of medications is addressed in a special manner when it comes to developing countries. Firstly, due to the social significance of medications, poor countries need them to be cheap and affordable, so drugs are
not protected as intellectual property objects in all countries.

The Doha Declaration (signed in 2001) to the Agreement on Trade-Related Aspects of Intellectual Property Rights made it possible for poor countries to delay bringing their legislation in line with the requirements of that Agreement thus protecting medications as intellectual property objects until 2016. Secondly, the institution of compulsory licensing is widely applied in poor countries to make use of technical solutions in medications [36].

The above-mentioned measures make it possible to release cheap medications onto the market, with the permission of the copyright holder at that, which, if parallel imports from those countries are allowed, can lead to a significant and unjustified reduction in drug prices in the developed countries. The restrictions imposed on the parallel imports of medications are therefore not only in the interests of consumer safety, but also in the interests of copyright holders.

Usually, the rules on allowing or prohibiting parallel imports are directly included in the legislation on intellectual property objects, most often in the articles related to the use of those objects (Australia, the Russian Federation, European legislation). Also, in some countries, in accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights, customs regulation measures are established, while some measures are included in the antitrust legislation.

In a number of countries, the rules related to parallel imports are enshrined in international treaties: both bilateral (the US-Australia Free Trade Agreement, the US-Morocco Free Trade Agreement) and multilateral ones (the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Treaty of Rome establishing the European Economic Community) [10,37]. That said, in the case of international legal regulation, countries are required, on the one hand, to comply with the balance of international obligations, the provisions of free trade agreements and the single economic space, the most favoured nation status, while on the other hand, they are required to adhere to the protection of intellectual property rights. In some cases, the rules governing parallel imports are established mainly through the judicial practice (EU) or the doctrine (Canada) [38].

One of the main ways to ensure the interests of copyright holders is the contractual regulation of issues related to parallel imports of the goods. That is, in contracts for the use of intellectual property objects (licensing, agency ones, etc.), as well as in contracts for the production and distribution of goods, in which certain intellectual property objects are used, the following issues may be settled:

- the territory where intellectual property objects are used by the person;
- the obligation of the person in question, when the product is put into circulation, to provide that the counterparty will take all necessary measures to ensure that the product is distributed and used in a certain territory only;
- pricing policy;
- responsibility for maintaining the quality of the goods [14].

That being the case, the conditions relating to the restriction of territory may be invalidated as leading to an artificial division of the market, while the conditions on pricing policy may be invalidated because of the use of a dominant position in the market. According U.S. experts, such contracts cannot be enforced in the EU, since the European Commission promotes the policy of creating a common European market.

4. CONCLUSION

The study of international experience regarding the functioning of global drug markets and conducting a comparative analysis of the activities of business entities in those markets is aimed at developing an efficient mechanism for identifying and terminating violations of the current competition legislation in pharmaceutical markets, in particular during bidding, which will ensure saving public funds and stimulate the development of competition in the pharmaceutical markets, which in turn should lead to lowering drug prices.

The threat to the lives of the citizens of the country caused by COVID-19 has contributed to the introduction in Ukraine of a number of rules aimed at ensuring the availability of medications and treatments that, under certain conditions, have consequences similar to measures of parallel imports or related to their use, in particular, the Law of Ukraine "On Amendments to Some Laws of Ukraine Concerning the
Treatment of the Coronavirus Disease (COVID-19)" [39]. With the consent of a COVID-19 patient, it is allowed to use medications unregistered in Ukraine at the time of his/her treatment, if their efficiency has been proven in other developed countries and they are recommended by the respective official body of the USA, European Union member states, the UK, Switzerland, Japan, Australia, Canada, China, Israel, while the Law of Ukraine "On Amendments to Some Pieces of Legislation of Ukraine Aimed at Providing Additional Social and Economic Guarantees in Connection with the Spread of the Coronavirus Disease (COVID-19)" [40] introduced amendments to the Tax Code of Ukraine that provide for the exemption from the value added tax of transactions for the delivery into the customs territory of Ukraine of medications, medical products and/or medical equipment necessary to implement measures aimed at preventing the occurrence and spread, bringing under control and eliminating of outbreaks, epidemics and pandemics of the coronavirus disease (COVID-19), according to the list approved by the Cabinet of Ministers of Ukraine.

For Ukraine, the introduction of parallel imports can be efficient in the short term. Allowing parallel imports of medications has significantly fewer negative consequences for the copyright holder, since the improper quality of the products, in which the invention is used without the use of a trademark, most often does not affect the business reputation of the patent owner. Nevertheless, the chosen model of permitting the use of parallel imports to ensure the availability of medications in Ukraine remains a topical and controversial issue that requires a lot of professional discussion. It is no secret that the introduction of parallel imports will lead, one way or another, to an increase in the volume of counterfeit products and the use of other measures of unfair competition in international trade. In addition, the issue of legalization of parallel imports is important not only in relation to the use of a trademark, but also regarding the use of other intellectual property objects, inventions, etc. Under such conditions, legislators should be very careful and cautious about the development and implementation of the institution of parallel imports of medications to Ukraine paying attention to the development of a whole system of quality and transparency control for procedures related to parallel imports to this country. In our opinion, stimulating the development of the domestic production and attracting foreign direct investment into the pharmaceutical industry of the country is the priority mechanism for ensuring the availability of medications for the country's population.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

Animal Ethic committee approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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