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## PHARMACEUTICAL INDUSTRY'S IP PROBLEMS AND PERSPECTIVES IN UKRAINE

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### ПРОБЛЕМИ ТА ПЕРСПЕКТИВИ ІНТЕЛЕКТУАЛЬНОЇ ВЛАСНОСТІ У ФАРМАЦЕВТИЧНІЙ ГАЛУЗІ УКРАЇНИ

*In the article we are considering the role and the current place of the intellectual property in the pharmaceutical industry in Ukraine. For doing that in the right way the role of IP in the global pharmaceutical industry was considered, within this question was highlighted the main tendency — constantly growing number of patents, and most of them are secondary. And researchers agreed, that the quality of patents for pharmaceuticals nowadays is lower than average, and lower than quality of the patents in other less mature fields. In the same time, pharmaceuticals also a high accounting rate of return worldwide, and in Ukraine as well. Looking on the situation inside the pharmaceutical market in Ukraine, we can claim that it is one of the fastest growing (have the second indicator of growth per year in Europe), and in spite of all challenges Ukrainian economy faces stays one of the most stable and the most promising area. Ukrainian pharma market has a significant export potential, high levels of investment and shows growing presence in foreign markets. All of these characteristics represents the great basis for the industry to grow and develop rapidly and effectively. But, this rapid growth and opportunity of entering European market slowed down by problems when it comes to intellectual property. According to the European Commission annual report on the situation with the protection of intellectual property in third countries, Ukraine is on the list of the biggest copyright infringers. There are legislative gaps in Ukraine in terms of protection of intellectual property rights and producers of original products, no or ineffective legal mechanisms to challenge unfair trademark registration, widespread transit of counterfeit and pirated products to EU markets. Among the industries most affected by copyright infringement, the European Commission's representatives are primarily pharmaceuticals. The only way to move forward and make over the situation is to provide fast changes to the legislation and to the norms of IP regulation. The Cabinet of Ministers of Ukraine approved the Concept of reforming the state system of legal protection of intellectual property in Ukraine, which defines the conceptual foundations of state policy in the field of intellectual property, including pharmaceuticals. This Concept envisages a number of changes in the system of public administration in the field of IP legal protection, that began to be actively implemented at the end of 2019.*

*У статті ми розглядаємо роль та сучасне місце інтелектуальної власності у фармацевтичній галузі в Україні. Для правильного розгляду ролі ІВ у світовій фармацевтичній промисловості було висвітлено основну тенденцію — постійно зростаюча кількість патентів, і більшість з них є другорядними. Ідослідники погодились, що якість патентів на фармацевтичні препарати нині нижча за середню та нижчу за якість патентів в інших менш зрілих галузях. У той же час фармацевтичні препарати також мають високий показник прибутку у всьому світі, а також в Україні також. Дивлячись на ситуацію всередині фармацевтичного ринку в Україні, можна стверджувати, що він є одним із найбільш швидкозростаючих (маємо другий показник зростання на рік у Європі), і, попри всі виклики, з якими стикається українська економіка, залишається однією з найбільш стабільних і найбільш перспективний район. Український фармацевтичний ринок має значний експортний потенціал, високий рівень інвестицій та демонструє зростаючу присутність на зовнішніх ринках. Усі ці характеристики є чудовою основою для швидкого та ефективного зростання та розвитку галузі. Але це стрімке зростання та можливість виходу на європейський ринок сповільнюються проблемами, що стосуються інтелектуальної власності. Згідно з щорічним звітом Європейської комісії про ситуацію із захистом інтелектуальної власності в третій країнах, Україна входить до списку найбільших порушників авторських прав. В Україні є прогалини в законодавстві щодо захисту прав інтелектуальної власності та виробників оригінальної продукції, відсутні або неефективні правові механізми для оскарження недобросовісної реєстрації товарних знаків, широкого транзиту контрафактної та піратської продукції на ринки ЄС. Серед галузей промисловості, які найбільше постраждали від порушення авторських прав, представниками Європейської комісії є насамперед фармацевтичні препарати. Єдиний спосіб просунути вперед та змінити ситуацію — це швидкі зміни до законодавства та норм регулювання ІВ. Кабінет Міністрів України затвердив Концепцію реформування державної системи правового захисту інтелектуальної власності в Україні, яка визначає концептуальні основи державної політики у сфері інтелектуальної власності, зокрема фармацевтичної. Ця Концепція передбачає низку змін у системі державного управління в галузі правової охорони інтелектуальної власності, які почали активно впроваджуватися наприкінці 2019 року.*

*Key words: intellectual property, pharmaceuticals, generics, patents, investment, legislation.*

*Ключові слова: інтелектуальна власність фармацевтика, дженерики, патенти, інновації, законодавство.*

## INTRODUCTION

One of the most profitable and fast-growing sectors of the world economy, which occupies a special place in the economic system of each country, is the pharmaceutical industry. This is due to the social significance of the products of this industry, the high degree of state regulation of the range and volume of its production, knowledge intensity and investment attractiveness of the industry.

Over the past 100 years, the private sector has developed almost all the drugs, therapies and vaccines available on the market. In the United States, for example, pharmaceutical companies' investment in research and development (R&D) has grown steadily over the past 15 years, leading to a doubling of spending by the state's National Institutes of Health. In Japan, the cost of research projects in the field of pharmaceuticals is 17.3% of sales, in the US this figure — 15.5%, in the European Union (EU) — 14.1%. No other industrial sector can boast of such intensive R&D activity. Compared to other industries, the pharmaceutical R&D industry accounts for most of the investment in research and development, even in times of economic and financial crisis [8].

Such innovation priorities are understandable; as pharmaceutical research plays a crucial role in improving public health around the world. Therefore, the cost of research projects in pharmaceuticals is constantly growing.

## ANALYSIS OF RECENT RESEARCH AND PUBLICATIONS

The current research is based on analytic data from European reports, like Report on the protection and enforcement of intellectual property rights in third countries [1]; Intellectual property Ukrainian National Office [19], and Official web portal of the Parliament of Ukraine [2;10].

About the pharmaceutical market in Ukraine and IP protection within it write Ukrainian researchers such as Androshchuk H., Rabotiahova L., Dukhovna O., Kondratiuk S., Kucherenko S., Tryfomenko M., Vorozhevich, A. [11—14; 16—18; 20—21].

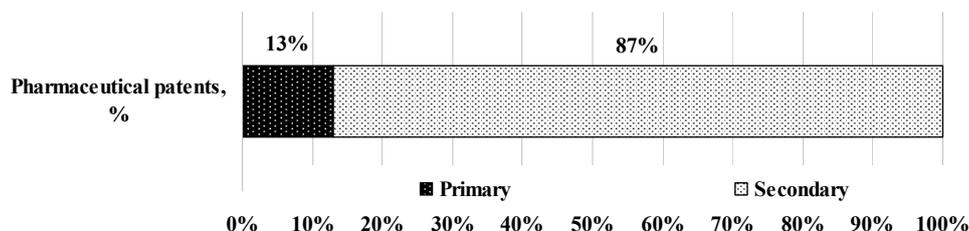
## FORMULATION OF THE OBJECTIVES

There is evidence that intellectual property regulation and protection plays a significant role in effective pharmaceutical industry functioning, in particular in Ukraine. Thereby, the main goal of the current research is analysis of exciting problems, and perspectives of improving IP regulation within Ukrainian pharmaceutical market.

## RESULTS OF THE RESEARCH

### THE ROLE OF IP IN THE PHARMACEUTICAL INDUSTRY

According to the analysis, today only 45% of issued patents for pharmaceuticals in the world are valid. For



**Figure 1. Number of primary and secondary pharmaceutical patents according to the European Commission report**

Source: compose by the authors based on [1].

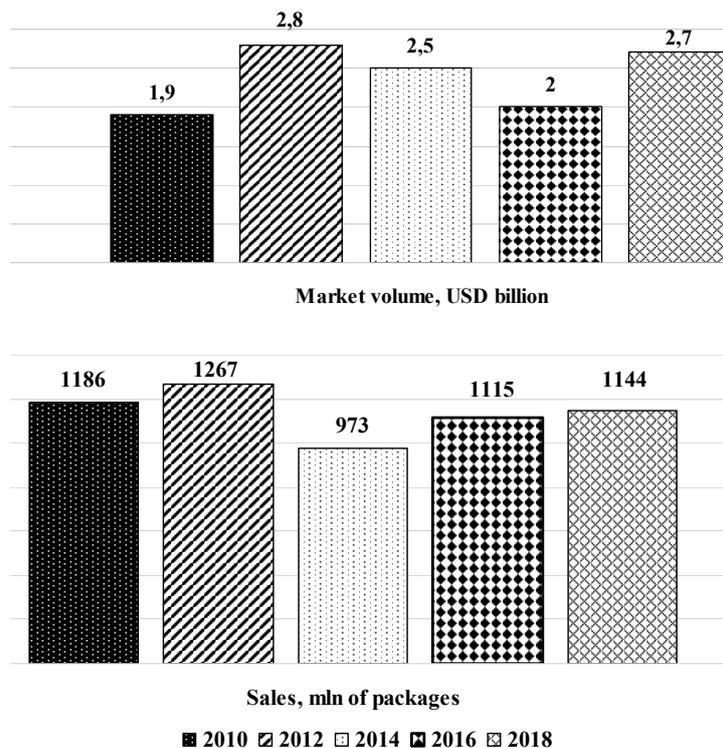
others, the term of legal protection has expired [21]. The share of truly innovative drugs in the world continues to decline. 90% of patented developments in this field are analogues — new dosage forms of known compounds or their new methods of application. According to the World Intellectual Property Organization (WIPO), since 2007, applications for inventions in the pharmaceutical industry have been steadily declining. 2012 went down in the history of the global pharmaceutical industry as a year of patent collapse — more than 40 brands lost patent protection with annual sales of about \$ 35 billion USA. According to expert estimates, by 2015, patent protection was lost to drugs blockbusters, the total annual sales of which is \$ 150 billion [11].

According to the report of the European Commission, the number of applications for pharmaceutical patents doubled, with 87% of them are secondary (see Fig. 1), i.e not for the active substance itself, but for the method of its production, dosage form and composition of relevant drugs, etc. This poses serious difficulties in creating generic versions. This was due to the following interventions: patent clusters (each drug can be protected by dozens of patent families); litigation with generic companies initiated by originator companies; bilateral agreements between generic and innovative companies to delay the introduction of generics into markets; patent management during the life cycle of drugs with the acquisition of new patents; interference with generics marketing permits.

At the same time, a characteristic feature of the pharmaceutical sector is also a high accounting rate of return, which is 2—3 times higher than the average of the companies on the Fortune 500 list. However, it should be borne in mind that along with the high rate of return for pharmaceutical companies is characterized by high growth in R&D investment. Despite the sharp rise in R&D spending in recent decades, the number of new chemical compounds (NHCs) being introduced into production worldwide, especially compounds that provide significant breakthroughs in medicine, has grown more slowly. Factors such as complications of diseases for which appropriate drugs are prescribed and complications of appropriate technologies play a role in this lag. OECD experts note that "the growing activity of patent activity has been accompanied by a decline in the quality of patents over the past two decades by an average of 20%," and that the quality of patents for pharmaceuticals is lower than average and lower quality patents in other less mature fields. Accordingly, the quality of patent applications filed by pharmaceutical companies in Ukraine and other countries and patents issued by offices remains low [16].

## UKRAINIAN PHARMACEUTICAL MARKET AS A FRAMEWORK FOR IP DEVELOPMENT

The pharmaceutical industry, according to the OECD classification, belongs to science-intensive industries and, according to Eurostat, is the world leader in high-tech industries in terms of gross value added per employee. At the same time, about 1/5 of all R&D expenditures in the



**Figure 2. Ukrainian pharmaceutical market volume and number of sales 2010—2018**

Source: compose by the authors based on [5].

**Table 1. Top 10 export countries of the Ukrainian pharmaceutical industry**

Country	Export volume, USD
Uzbekistan	41,000.000
Kazakhstan	19,000.000
Russia	19,000.000
Brazil	17,000.000
Belarus	16,000.000
Moldova	14,000.000
Azerbaijan	11,000.000
Georgia	9,000.000
Kyrgyzstan	5,000.000
Iraq	4,000.000

Source: compose by the authors based on [5].

world are accounted for by pharmaceutical production. The pharmaceutical market in Ukraine is one of the fastest growing — 15—20% per year. This is the second indicator among the CIS countries. The drug market is one of the few in Ukraine that is developing dynamically. Ukraine is one of the largest drug manufacturers in Eastern Europe. The pharmaceutical market is of the economy: despite the devaluation of the national currency, which has tripled, military action, declining incomes, the market continues to grow in the national currency.

Pharmaceuticals in Ukraine is an industry that develops the national economy. It employs only 0.15% of the total number of employees, but they create 0.83% of the country's GDP and provide UAH 24 billion in value added [12]. Figure 2 shows Ukrainian pharmaceutical market volume and sales.

It can be argued that the Ukrainian pharmaceutical business overcame the crisis of 2014 and is rapidly recovering. Over the past three years, the industry has grown by an average of 11% per year, which is three times faster than Ukraine's economy as a whole.

Ukrainian pharmaceutical industry has enormous potential. The market will grow not only quantitatively but also qualitatively. Ukrainian pharmaceutical companies are looking for foreign strategic partners to gain access to modern innovative technologies; and are negotiating with the state to participate in government programs to develop new drugs. Global annual sales of medicines are projected to grow from the current \$ 911 billion to \$ 1.25 trillion by 2024. Ukraine will be part of this growth.

Pharmaceuticals is one of the three leading industries in terms of investment, second only to the food industry. For every 100 hryvnias of added value created, there are 19 hryvnias of capital investments. The volume of investments in pharmaceutical production has not yet reached the pre-crisis level, but the level of their intensity is higher than the average for the sectors of the Ukrainian economy.

In the world ranking of pharmaceutical exporters in 2017, Ukraine ranked 61st with \$ 0.18 billion. This indicates a significant export potential of Ukrainian pharmaceuticals; whose production is GMP certified.

In 2018, Ukrainian pharmaceutical products were sold to 81 countries (export geography shown at the Table 1), while in 2017 — only up to 50. Export sales in 2018 amounted to \$ 184 million. Top destinations for the export of pharmaceutical products remain organic markets of CIS countries, but market players actively explore other regions, including the Middle East, Asia-Pacific and EU countries. During 2016-2018, Ukrainian pharmaceutical manufacturers received nine GMP certificates from the regulatory authorities of EU member states, which is a prerequisite for entering European markets.

The domestic market is characterized by a high level of competition and a low level of consumption of medicines per capita. Its growth is slowed by low incomes, high over-regulation and incomplete health care reform. 99% of the cost of medicines in Ukraine is financed directly by the population, while in European countries a significant share

of the cost is covered by health insurance and government programs. Drug consumption per person in Ukraine is \$ 73, which is about 10 times less than in the United States. In 2018, Ukraine reached the pre-crisis level of 2014 on this indicator. The driver of change may be the development of health insurance and the Affordable Care Act.

Pharmaceutical markets continue to be one of the most controlled by government agencies. The Antimonopoly Committee of Ukraine has historically paid special attention to the development of pharmaceutical markets. Among the most pressing issues addressed by the regulator over the past few years is the distribution and advertising of medicines. As practice shows, not all claims of state bodies to market players can withstand inspection in the courts. The presence of positive experience in appealing by market players to unfounded decisions of regulatory bodies is one of the signs of the development of the rule of law and the independence of branches of government.

The strengths of the Ukrainian pharmaceutical industry are the capacity of the domestic market, significant experience in the manufacture of medicines, growing presence in foreign markets, as well as the availability of the full range of basic pharmaceuticals, the necessary scientific and educational base and qualified personnel.

87% of the market is retail. In their structure, almost a third of the market is in the top 10 companies, six of which are Ukrainian manufacturers. In general, the share of domestic companies in the structure of retail sales is 72% in physical terms and 38% in cash [15].

Foreign companies dominate in segments where they have protective patents for products, where there are technological barriers in the production of drugs, as well as in cases where domestic companies do not have the economic feasibility of entering the market. All other market segments are being mastered by domestic industry at different speeds.

For the fourth year in a row, there is a growth of the pharmacy segment — both in kind and in monetary terms. According to the results of 2018, pharmacy sales increased by 17.5% compared to pre-crisis 2014 and reached 1.14 billion packages.

Today, pharmaceuticals are the industry that helps to improve the country's welfare. Its growth can be compared with the growth of the best economies in the world — 11% per year, i.e three times faster than the economy of Ukraine.

Drug development is a high-tech field, and the industry itself is innovative. This industry creates a product with a long value chain and high added value. In 2018, the industry generated UAH 24.6 billion in GDP. In some countries (Ireland, Singapore) it is a driver of economic growth and accounts for a significant share of GDP. In Ukraine, pharmaceuticals could be even more visible if the state relied on high value-added industries. Currently, there are factors holding back the growth of the industry, in particular, high taxation. The tax burden on the industry is 5 times higher than on the extractive industry and 18 times higher than on agriculture [15].

Returning to the issue of extending existing patents, it should be noted that the analysis shows that extending the additional patent for drugs to five years in developing countries, including Ukraine, leads to additional costs from national health budgets and negatively affects patients' access to drugs. On the example of one drug, we calculated that an additional saving of 20% would be possible if the generic version became available immediately after the patent for the original drug expired. At the same time in Ukraine for the period from 01.01.2013 to 01.10.2018 was extended (by court decision) the validity of 128 patents for inventions, the objects of which are medicines. Analysis of the dynamics (for 2011-2015) of the receipt of applications for inventions in the field of "Drugs" from foreign applicants shows that their number is four times greater than the number of national applicants, and the issuance of patents — almost three times. This indicates a long-term patent

expansion of foreign companies in the pharmaceutical market of Ukraine.

The dynamics of the number of valid patents for inventions in the areas of "Medical Equipment" and "Drugs" by years of maintenance showing, that the extension of patents for inventions, the objects of which are drugs, continues to grow [17]. Pharmaceuticals is an innovative industry. The main Ukrainian manufacturers are certified according to the international GMP standard (Good manufacturing practices) and direct significant funds to research and development. Capital investments in Ukrainian pharmaceutical production in 2017 alone amounted to UAH 1.85 billion [12]. Currently, Ukrainian pharmacists are conducting more than 400 clinical trials to create new drugs.

More than 90% of drugs are technologically obsolete, in which the 20-year term of patent protection has already expired. Foreign pharmaceutical companies are blocking the entry of cheap medicines. Cases of unfair competition have become more frequent: seizures of pharmaceutical companies by force, attempts to change the management of enterprises by "their" managers, sale of important state assets offshore, embezzlement of state shares, blocking the entry of domestic drugs into domestic and international markets, growing uncontrolled turnover [13].

## PHARMACEUTICAL IP PROBLEMS VS PERSPECTIVES IN UKRAINE

In January 2020, the European Commission published an annual report on the situation with the protection of intellectual property in third countries [1]. According to this document, Ukraine is on the list of the biggest copyright infringers. The worst situation with the protection of intellectual property is only in China, which took first place in the black list. According to the European Commission, there are legislative gaps in Ukraine in terms of protection of intellectual property rights and producers of original products, no or ineffective legal mechanisms to challenge unfair trademark registration, widespread transit of counterfeit and pirated products to EU markets. And most often it concerns medicines.

Among the industries most affected by copyright infringement, the European Commission's representatives are primarily pharmaceuticals. First, there is a requirement in Ukraine that obliges drug manufacturers to obtain a separate marketing authorization for a product within two years of obtaining such authorization in any country in the world. This is a discriminatory condition that creates additional obstacles for foreign companies to enter the Ukrainian market.

Secondly, there is no adequate regulation of the generics segment. These are copies of the original drugs, with a similar composition, but under a different name. Most often in our country the release of such drugs is despite bans and restrictions.

One of the biggest problems is counterfeit drug production. In second place — the release on the Ukrainian market of products that use someone else's patent or someone else's mark. Or a designation similar to the degree of confusion with someone else's registered mark [18]. This is probably one of the most common categories of disputes in Ukrainian courts over intellectual property in pharmaceuticals.

Counterfeit products also cause a lot of difficulties for pharmaceutical companies. The Ministry of Health of Ukraine does not announce data on the number of counterfeits in the domestic market, but, according to the World Health Organization [9], more than 10% of medicines in low- and middle-income countries (including Ukraine) are counterfeits.

Patent rights to drugs are the main asset of pharmaceutical companies. But imperfect legislation and high levels of corruption in regulators mean that drug manufacturers are forced to put up with theft of their intellectual property because they see the prosecution of

violators as a hopeless affair. Formally, the law does not allow the sale of drugs that infringe intellectual property. But until recently, this situation was widespread. In addition, without the involvement of law enforcement agencies, the perpetrator will never be prosecuted. Such cases are investigated by the police, but they do not have special units that have the necessary knowledge of the nuances of copyright and specific procedural skills for this category of cases.

Any drug must undergo certain authorization procedures before being placed on the market. The Ministry of Health and its structures are responsible for them. But the fact is that the ministry, in fact, does not regulate intellectual property rights. So, they can't track their violations.

For example, in the United States there is a procedure called patent linkage. Its essence is that the state combines the efforts of two bodies. This is the regulator and IP-agencies that deal with the inspection and admission of drugs to the market. Then the tasks are solved quite effectively. In the case of generics, the patent linkage allows almost the day after the expiration of the patent to bring the product to market without wasting time. For the originator, this solves the issue of uncontrolled release of unscrupulous generics — those who illegally use existing patents.

In Ukraine, generic manufacturers often do not wait for the patent to expire. Instead, they register the drug and enter the market before the patent has expired, in the hope that the remaining patent will be valid in litigation. And thus gain time and get a couple of years of life in the market.

The need to amend the legislation on intellectual property in the pharmaceutical industry is long overdue, both through the issuance of so-called "evergreen patents" and the possibility of patenting diagnostic and treatment methods, and through a number of other provisions of current law that do not meet international best practice.

Some drugs are protected by patents that do not protect the active substance itself and in some way directly affect the therapeutic efficacy, but "evergreen" patents relating to methods of treatment, methods of manufacture of the substance, already known combinations of active substances and the like.

Vital medicines in Ukraine are sometimes several times more expensive than in neighbouring countries, and this is due to the fact that a patent for a drug that has long exhausted itself in the world continues to operate in Ukraine. These are the so-called "evergreen patents", which establish an additional monopoly on what has long been known.

In recent years, senior officials have repeatedly stated that the current system of public administration in the field of intellectual property has demonstrated its inefficiency and inability to ensure development, and the state of protection of intellectual property rights in Ukraine has received many comments from international partners (US and EU) [14]. That is why on June 1, 2016 the Cabinet of Ministers of Ukraine (hereinafter — CMU) by its order № 402 ? approved the Concept of reforming the state system of legal protection of intellectual property in Ukraine [5], which defines the conceptual foundations of state policy in the field of intellectual property, including pharmaceuticals.

The approved Concept envisages a number of changes in the system of public administration in the field of IP legal protection. Despite the fact that more than four years have passed since the adoption of the Concept, important and driving changes, both for IP in general and in the pharmaceutical industry, began to be actively implemented at the end of last year.

In 2019, a draft National Strategy for the Development of Intellectual Property in Ukraine for the period 2020-2025 was developed, which defines the vision and prospects of the national intellectual property system, strategic goals, ways to achieve them and actions for their implementation [4]. This strategy was officially presented on 6.11 at the Innovation Market 2019 [3].

The National Intellectual Property Strategy identifies the current state and problems and aims to identify the necessary conditions for the successful completion of legislative, institutional and judicial reforms in the field of intellectual property to create, protect, manage, commercialize intellectual property, maximize the potential of intellectual property in the future; innovation development, creation of an effective system of protection of intellectual property rights, support of invention, raising the level of education and culture and popularization of knowledge in the field of intellectual property, which would generally promote the development of national competitive digital economy based on knowledge, innovation and creativity. attractiveness.

The steps envisaged by the Strategy are aimed at ensuring Ukraine's integration into the international and European intellectual space, taking into account Ukraine's national interests.

Regarding the issue of intellectual property in the field of pharmaceuticals, the strategic goals of the National Strategy are: development of a system of legal protection of intellectual property in Ukraine, which should promote the balance of public interests, right to life and health and property interests of patent holders; comply with international best practices and build on strict patentability criteria prepared by UNDP and WHO; to ensure the fair use of patent rights and fair competition in the market of medicines; reduce the financial burden on the state budget in providing medicines to the population; to promote the development of the national pharmaceutical industry.

Also identified a number of specific measures to achieve certain goals, namely: reforming patent law and legislation in the field of legal regulation of the market of medicines as one of the key legal mechanisms to ensure the balance of property rights of patent owners and the right to life and health through public access to medicines, with the solution of the following problems [4]:

- i. establishing the specifics of the examination of inventions subject to medicinal products for compliance with the conditions of patentability, in order to avoid the issuance of new patents for inventions that are not innovative, but contain only minor modifications to existing patents, with little improvement in efficiency (" evergreen patents ") and the introduction of a mechanism for joint examination of the patent application for a medicinal product with the health authority (SE State Expert Center of the Ministry of Health of Ukraine) in terms of confirmation of non-obviousness (inventive step), industrial suitability of the medicinal product, the presence or absence of a new therapeutic effect;

- ii. optimizing the procedure for compulsory licensing of rights to inventions to which medicinal products are objects;

- iii. abolishing the need to verify the patent status of medicinal products during their state registration for entry into the market;

- iv. implementation in the legislation of Ukraine of the "Bolar" provision, according to which companies are allowed to apply for state registration of a generic medicinal product before the expiration of the patent for the original medicinal product; after the expiration of the patent, the company can immediately begin the introduction of a generic drug, which allows to reduce the time;

- v. the introduction of a parallel import regime for medicines;

- vi. the introduction of the possibility of restricting the exclusivity regime of these medicinal products in the public interest;

- vii. the introduction of additional legal protection of inventions, taking into account the experience of its mitigation and the introduction of the possibility of contract manufacturing of pharmaceutical products for export during the validity of supplementary protection certificates.

On February 5, 2020, the Verkhovna Rada of Ukraine supported in the first reading the draft Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine (Regarding the Reform of Patent Legislation)" [7].

On June 16, 245 people's deputies voted for the corresponding bill № 2255, and on August 14 the President of Ukraine Volodymyr Zelensky signed this law [2; 10].

The law aims to create an optimal, high-quality and effective state system of legal protection of intellectual property, able to form, implement a transparent public model of overcoming challenges and risks and offer effective tools in the field of intellectual property as incentives for related economic and social factors.

The law provides for the establishment of the National Intellectual Property Authority of Ukraine (NIPO) as a legal entity under public law, which belongs to the sphere of management of the Ministry of Economy [19]. The relevant ministry will ensure the formation and implementation of state policy in the field of intellectual property, and NSSI will perform certain public functions for the implementation of state policy (issuance of protection documents for intellectual property rights). Thus, after the adoption of the law, the NIPO will be endowed with appropriate powers at the legislative level.

Importantly, the Bill radically changes the state policy in the field of legal protection of inventions in medicine and pharmacy, forming it on the basis of the priority of public interests in access to treatment over intellectual property rights.

A breakthrough position for the domestic pharmaceutical industry and for the domestic patient is the restriction on the patenting of new forms of known substances of drugs. It is important that the Bill also provides for the elimination of treatment, diagnosis, and surgical interventions among the objects of patenting.

Important for expanding and accelerating competition in the market of medicines is the provision of the bill on the introduction of the so-called "Bolar" principle, according to which all preparatory procedures for the registration of a generic drug can be initiated during the patent protection. This usually occurs in the last year of the original drug patent. The relevant competent authority analyses the dossier of the generic medicinal product, which may take up to a year, but the registration certificate is issued only after the expiration of the patent, but due to the fact that all expert studies have been conducted, registration may take place the day after expiration. This means that the generic drug will compete with the original much earlier.

Article 27-1 also regulates additional patent protection of medicines after the expiration of the 20-year patent: at the request of the patent owner will be issued a certificate of additional protection for a period to be determined by law and with the possibility of extending such rights in paediatrics for 6 months [20].

Thus, additional legal protection of inventions was introduced to compensate the patent owner for the period of time since the patent was already valid (and its term began to expire), and the owner could not enter the market and start making a profit due to the need for permits and registration of the drug. It is important that such a permit has only a basic patent. This is exactly what is envisaged in the Bill.

The legislation on the possibility of appealing applications for inventions, the so-called "pre-grant" opposition, was also implemented from the EU legislation into the Bill. To ensure fair competition in the market, it is extremely important to eliminate the abuse of patent rights both at the application stage and through the issuance of evergreen patents. This amendment to the Bill applies to all patent applications, not just pharmaceuticals. The possibility of appealing an application that infringes the rights or legally protected interests of a certain person provides an opportunity, without waiting for the grant of a patent, to stop the abuse of intellectual property rights by

filing an objection to the appropriate authority. Appeals to patents have already been a lengthy process that can take years, and the pre-grant opposition will allow the patent to be considered in a short time to meet the patent's criteria for novelty, inventive step, industrial applicability and other legal requirements.

## CONCLUSIONS

We have determined that today in Ukraine, there are enough unresolved problems to protect intellectual property. This includes Internet piracy, lack of protection of intellectual property rights on the Internet, lack of normal mechanisms for fixing such violations, and effective tools for protecting intellectual property rights, "patent trolling," etc. To solve these problems, IP should become a fundamental tool for creating an enabling environment for innovation, ingenuity, creativity and free competition, economic and cultural development of Ukraine, strengthening its scientific potential, increasing the level of investment attractiveness country.

In general, increasing the level of protection of intellectual property rights provides for the implementation of many complex tasks related to both improving national legislation and law enforcement practice, completing institutional reforms, as well as establishing active interaction between authorized government bodies, law enforcement, fiscal, customs authorities, etc. A significant role in this process is also assigned to the judicial branch of government, which is in the stage of active reform, especially considering the prospect of the commencement of the activities of the High Specialized Court on Intellectual Property in Ukraine in 2020 and the existing reform of procedural legislation, as a result of which most IP infringement disputes are considered the order of economic jurisdiction. Despite the fact that two forms of IP protection are used in Ukraine — jurisdictional and non-jurisdictional, the latter is considered ineffective due to low legal culture. Protection of IP rights can be carried out in the administrative-legal, criminal-legal, economic-legal, civil-legal order. However, a common problem for all aspects of the protection of intellectual property rights is the inconsistency of the normative legal acts that regulate the legal relationship on OPIV by the norms of the Association Agreement, the "obsolescence" of certain provisions of these acts. The long process of implementing European approaches in this area, which has not yet been completed, causes complications in building an effective mechanism for protecting IP rights. Along with this, the weak point of the national policy for the protection of IP is the prevention and counteraction of administrative and criminal offenses in the field of relevant rights, which leads to a serious imbalance in the measures of state coercion in this area and inadequate protection of rights to OIP.

The main directions for improving the state of IP should be the successful completion of legislative, institutional and judicial reform in the field of IP for creation, protection, management, commercialization of IP, maximizing the potential of intellectual property, creation of an effective system for the protection of intellectual property rights, support inventions, raising the level of education and culture and promoting knowledge in the field of intellectual property, would generally contribute to the development of a national competitive digital economy based on knowledge, innovation, and creativity, and also increases its investment attractiveness.

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