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# The role of intellectual property in the post-war development of the health care sector

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## Abstract

Understanding the role and necessity of the use of intellectual property in the field of medicine is the basis for the proper development of this field in the postwar period, as well as for the entire healthcare system. Therefore, the purpose of the study was to determine the impact and prospects of the use of intellectual property in the development of the Ukrainian health sector, post-war. The methodological basis of the work consists of general and special scientific methods: analysis and synthesis, generalization, dialectical, axiological, legal-formal, legal-comparative and structural system. The result of the work shows the necessity of using heterogeneous objects of intellectual property, in particular, those in the field of copyrights and patents, for adequate reform and effective modernization of the health sector. It is concluded that intellectual property is designed not only to ensure the property and non-property interests of the subject of the specified property, but, in addition, is intended to ensure the needs of society in general in the appropriate sphere, where the objects of intellectual property find their concrete application.

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**Keywords:** intellectual property; copyright; patent law; invention in medicine; large-scale invasion.

## El papel de la propiedad intelectual en el desarrollo del sector sanitario en la posguerra

### Resumen

Comprender el papel y la necesidad del uso de la propiedad intelectual en el campo de la medicina es la base para el desarrollo adecuado de este campo en la posguerra, así como para todo el sistema sanitario. Por lo tanto, el propósito del estudio fue determinar el impacto y las perspectivas del uso de la propiedad intelectual en el desarrollo del sector de la salud de Ucrania, en la postguerra. La base metodológica del trabajo consiste en métodos científicos generales y especiales: análisis y síntesis, generalización, sistema dialéctico, axiológico, jurídico-formal, jurídico-comparativo y estructural. El resultado del trabajo muestra la necesidad de utilizar objetos heterogéneos de propiedad intelectual, en particular, aquellos que se encuentran en el ámbito de los derechos de autor y patentes, para la adecuada reforma y modernización efectiva del sector de la salud. Se concluye que la propiedad intelectual está diseñada no sólo para garantizar la propiedad y los intereses no patrimoniales del sujeto de la propiedad especificada, sino que, además, tiene por objeto garantizar las necesidades de la sociedad en general en la esfera apropiada, donde los objetos de la propiedad intelectual encuentran su aplicación concreta.

**Palabras clave:** propiedad intelectual; derechos de autor; ley de patentes; invención en medicina; invasión a gran escala.

### Introduction

The study is devoted to the importance of intellectual property objects in the field of health care during the recovery of Ukraine after the full-scale war with the Russian Federation. Thus, despite the fact that the prospects and deadlines for the end of hostilities are currently not clearly defined, there is already a need to build structured plans for the post-war reconstruction of the state and develop mechanisms for their implementation. The sphere of health care is no exception, which is an important segment in the everyday life of normal civilized society.

The full-scale invasion of the Russian Federation on the territory of Ukraine changed the outlook not only of Ukrainians but also of the whole world. From now on, security issues occupy the most important position among other issues of domestic and foreign policy, since its provision is the main condition for the successful implementation of all other vectors of public life.

The end of the military conflict will have the consequence of rethinking many internal and external processes in various spheres, in particular in the sphere of health care. This area should be one of the first to be modernized, since, firstly, after hostilities, many soldiers and civilians who suffered from the actions of the aggressor state will need treatment and rehabilitation, and secondly, the pro-European vector of Ukraine, which gained new momentum during the full-scale invasion, demands compliance of the medical field of Ukraine with the high standards of the European Union (hereinafter referred to as the EU).

The purpose of the study is to determine the impact and prospects of the use of intellectual property in the post-war development of the healthcare sector of Ukraine.

## **1. Theoretical Framework or Literature Review**

The issue of the use and importance of intellectual property in the field of medicine and biotechnology has been repeatedly studied by many scientists, each of whom focused on the appropriate aspect of such use, thereby contributing to a common theoretical base on this topic.

For example, the contribution of Kashintseva (2013), whose huge number of works are devoted to various manifestations of intellectual property in the field of health care, both within the limits of copyright and patent law, is invaluable. As a candidate of legal sciences, and an active employee of the Research Institute of Intellectual Property of the National Academy of Sciences of Ukraine, the latter studied, in particular, the principles of the legal protection of intellectual property in the medical and pharmaceutical market from the position of priority of human rights, determined the relationship between human rights and the right to patent methods of diagnosis and treatment, established the features of an author's work on medical topics, insisted on the need to take into account the public interest when granting an exhaustive intellectual property right to a socially important object in the field of medicine.

Thanks to her, the theoretical base of the subject of this study was supplemented with a strong, well-founded position on the shift of priorities towards the accessibility of the achievements of modern medicine and pharmacy to society.

The works of Hlushchenko (2017) made a similar contribution to the mentioned topic, which detailed and summarized the features inherent in the objects and subjects of intellectual property in the field of medicine and biotechnology.

Problematic questions of the patent law in the field of medicine were reflected in the works of K. Datsko (2018), where there is an analysis of the norms of Ukrainian national and foreign legislation in this field within the framework of the classification of objects of intellectual property law in medicine and their tools, requirements for their recognition and protection, a complex of special procedures and measures, which are used not only for marketing and capitalization of the medical business but are also a means of providing domestic medicine with high-quality pharmaceutical products and the involvement of modern methods of treatment.

Korogod and Novorodovska (2020) supplemented the specified base by comparing the foreign practice of using objects of intellectual property rights in the field of biotechnology, in particular by studying the user experience of the USA and Japan, which can be considered leading states in the use of an intellectual property. The peculiarities of the functioning of the biotechnology industry in China, India, Switzerland, and the countries of Western Europe were also investigated.

According to the fact of carrying out the specified comparison of state policies, scientists focused on the possibility of effective development of the intellectual property market with the help of Internet technologies, university spin-off companies, transfer of technology and movement of human capital, and proper financing of the mentioned processes.

With the joint efforts of such personalities as V. Teremetskyi, A. Matviychuk, O. Muzychuk, M. Shcherbakovskiy, and O. Oderii (2019) the peculiarities of the legal protection of medical inventions were clarified, the prospects for its improvement were determined, the balance of interests, the rights of patients and patent holders were additionally analyzed, the need for the implementation of the norms of international law and the law of the European Union into the legislation of Ukraine was established. Scientists have proven that objects of intellectual property in the field of medicine have a species division and must meet ethical requirements.

The problems of private law in modern Europe, including the problems of the intellectual property institute, were considered by Kharytonov *et al.* (2019).

However, the waging of a full-scale war on the territory of Ukraine led to the emergence of a new vector of studying intellectual property objects in the field of health care, which consists of the study of their application in the post-war reconstruction of the state. Given the fact that the issue of the restoration of the state after the war began to arise relatively recently,

full-fledged research within the chosen topic is currently lacking, therefore there is an urgent need for additional study of the importance of intellectual property in the field of health care during the period of restoration of independent Ukraine.

## **2. Methodology**

Achieving the above research result became possible due to the combined use of general scientific and special methods of scientific knowledge.

Thus, with the help of the dialectical method, a general idea of intellectual property in the field of health care was formed, which consists in establishing a system of its properties, connections, and regularities that are manifested in the mentioned field.

The analysis and synthesis served as the basis for characterizing the features of the use of individual intellectual property objects in medicine, which made it possible to draw conclusions about the prospects for their use in post-war development.

The axiological method made it possible to assess the importance of the health care sphere for Ukraine to realize its own integration goals and strengthen it as a sovereign state, and also helped to establish the importance of the specified intellectual property processes.

System-structural analysis revealed the content of the main objects of intellectual property in the field of medicine and determined the plane of their application. The specified method, in particular, became the basis for proposing different classifications of the investigated objects according to separate independent separation criteria.

The formal-legal method, in turn, also helped to clarify the essence and content of the main concepts on which the research is based, in particular, as an object of intellectual property and a medical invention.

With the help of the functional method, the purpose of intellectual property was determined for the proper functioning and development of the state in the period of post-war development and after it; the vectors of using the results of intellectual mental activity are determined.

Comparison of intellectual property objects of any other sphere with such objects in the field of health care became possible due to the comparative legal method. Thus, it was established that the objects of intellectual property in the field of medicine have a number of features that distinguish them from the same kind of objects in other spheres of social life. The specified method helped to identify the shortcomings of the legislation on intellectual property.

The method of generalization also contributed to the identification of shortcomings and problematic issues in the field of application of intellectual property in the field of medicine, which in turn made it possible to draw attention to the need for their urgent solution in the period of post-war development, in particular by changing the vector of domestic policy within the scope of patenting inventions and useful models.

### **3. Results and Discussion**

The current stage of human development is characterized by instability associated with radical changes in world politics, economics, law and many other spheres of public life (Tkalych *et al.*, 2022). The field of medical care in different countries of the world is also undergoing significant changes.

One of the most effective ways to modernize and improve the healthcare sector is the active development and application of intellectual property objects in medicine.

The definition of the concept of an object of intellectual property is not established either in the Civil Code of Ukraine (Law 435-IV, 2003) (hereinafter referred to as the Civil Code of Ukraine) or in any other Ukrainian legal act. At the same time, Part 1 of Article 418 of the Civil Code of Ukraine establishes that the right of intellectual property is the right of a person to the result of intellectual, creative activity or to another object of intellectual property right, defined by this Code and another law. Thus, the legislator understands the object of intellectual property rights, in particular, as the result of a person's intellectual and/or creative activity. However, the result of such work is not always the object of intellectual property.

In order to bring clarity to this issue, the legislator fixed in Article 420 of the Civil Code of Ukraine an approximate list of those objects that can be considered an object of intellectual property. This list is approximate because the active development of the innovation sphere, in particular with the help of information technologies, leaves the niche of the intellectual property open for new objects that may be different from those already known and established at the legislative level.

Objects of intellectual property can be classified as complex objects of civil turnover since their existence and registration of such existence are associated with the presence of a large number of nuances. Thus, the object of real property is a material substrate that is limited in space and is used by a certain number of persons; in contrast, the object of intellectual property is an ideal substrate that exists in an immaterial form on a material medium (Kozyakova, 2008).

Objects of medical intellectual property, which represent material and other goods in such a field, which satisfy the relevant interests and needs of citizens and organizations and regarding which subjects of intellectual property in the field of medicine and biotechnology enter into defined legal relations and perform the necessary sub-objective rights and obligations (Hlushchenko, 2017), occupy an important place in the field of health care. Such objects can be divided into two main groups according to species characteristics:

- 1) objects of copyright, and;
- 2) objects of patent law.

Of course, the specified gradation is conditional, but it shows the main vectors of the use of intellectual property in medicine for the purpose of its improvement. Other objects of intellectual property, which are not included in the specific groups outlined above, can also be used in the field of health care, but it is not yet possible to imagine their use, since such examples are currently unknown in practice.

The first main group of intellectual property objects in the field of health care consists of copyright objects, which in this field should include:

- materials used in public presentations (theses, reports, lectures, seminars);
- results of conducted scientific research (scientific articles, dissertations, monographs);
- design and technological documentation for medical devices and instruments;
- reports on pre-clinical and clinical examinations of medicines and medical devices, regulatory documents;
- advertising brochures, methodical manuals, and guidelines for doctors;
- graphic demonstrative materials of the treatment process (pictures, drawings, illustrations);
- audiovisual demonstrations of medical interventions, photographic works, and slide films illustrating modern medical technologies, and;
- computer programs for medical and diagnostic profiles (Popovych and Koshova, 2021).

It is these objects of copyright that are necessary, in particular, for the study of various diseases and injuries, the consequence of which may be the invention of an effective method of treatment, which is why, in the opinion

of the author, such objects of intellectual property should be placed in public access as much as possible on publicly known platforms of doctors and other specialists in the field of health care.

Along with this, the situation of uncontrolled access to the object of copyright in the field of medicine may violate certain material interests of the author, who owns non-property and property rights to his object, however, in the opinion of the author, the social necessity of these results of intellectual activity should prevail over such an interest, in connection with which it is not necessary to limit access to the specified objects of copyright. Instead, it is expedient for an authorized entity from the state to consider the possibility of developing and implementing a mechanism for compensating the author for the material costs incurred by the latter due to open access to intellectual property objects in the field of health care, the author of which is himself.

Objects of patent law in medical practice include inventions. An invention is the result of a person's intellectual activity in any field of technology, which has novelty, inventiveness, and industrial applicability. The novelty of the invention does not limit territorial framework, it must have an absolute global character. Novelty is assessed not only by previously registered inventions or utility models but also by publicly available sources of information, including publications and articles. The inventive step is a non-obvious way of obtaining a technical solution that does not have to follow the existing state of the art. Industrial suitability is the possibility of using the invention in the treatment process (Popovych and Koshova, 2021).

The most common objects of inventions in medical practice are a product (device, substance) or process (method): devices for treatment and diagnostics; medicines; strains of microorganisms used for disease diagnosis or treatment; biotechnological inventions.

Medical devices include devices and apparatus for diagnostic and therapeutic purposes; surgical, ophthalmological, and other special instruments; equipment of operating rooms, laboratories, diagnostic and other offices; devices for physiotherapy and massage; x-ray equipment; medical products: prostheses, tires, bandages, hearing aids (Kashintseva, 2014).

The variety of intellectual property objects that can be used in the field of health care indicates the need for the development of such innovations both in the present time and in the post-war period since such inventions affect the possibility of receiving proper medical care and increase the level of the possibility of treating various human health disorders.

The specified variety of inventions for ease of classification can be conditionally divided into:

1. pharmacological, where the objects of intellectual property will be new or improved pharmaceutical preparations;
2. microbiological, accompanied by the study of various types of microorganisms (viruses, bacteria);
3. procedural, represented by ways and methods of diagnosis, prevention, and treatment, and;
4. technical-instrumental, representing a set of devices and tools used in medical practice.

Analysis of the Specialized Database of the State Enterprise “Ukrainian Institute of Intellectual Property” “Inventions (useful models) in Ukraine” by the search query “treatment” shows that the most popular intellectual property objects of patent law are methods of treatment, followed by devices for treatment, methods of medical diagnosis and forecasting of human diseases, strains of microorganisms, viruses, fungi. One of the examples of such a patented invention is the patent “Method of treatment of pulmonary tuberculosis” (patent No. 1808), which belongs to the Ukrainian Research Institute of Phthiatriy and Pulmonology named after F. G. Yanovsky (Teremetskyi *et al.*, 2019).

It is likely that in the period of post-war development, intellectual property objects in the field of health care, which will relate to the psychological and psychiatric component of human health, will become even more popular, since the full-scale militarized attack of the Russian Federation on Ukraine, which is accompanied by unprecedented cruelty and inhumane treatment of human rights and freedoms, aggravated both the general psycho-emotional state of the entire Ukrainian society and the state of its individuals who were directly affected by the criminal actions of the aggressor state, or suffered an irreparable negative impact as a result of their own excessive empathy and emotional instability.

At the same time, only relatively uniform active activity within each specified group will allow bringing the healthcare sector to a new level, which will be characterized by an adequate level of providing the population with high-quality medical services.

At the same time, it is worth noting that inventions in medical practice differ from other inventions in the field of industrial application, which determines their special status among objects of intellectual property that are used in other spheres of social life. Medical inventions have a special field of application - this is medical practice. Application of the invention in medical practice has a direct connection with human rights, in particular the patient's right to life and health care.

Therefore, medical inventions have a peculiarity, which is that they have their own species division determined by the field of application of the

invention (method of treatment and diagnosis); medico-biological or clinical research (tests) must take place in medical facilities, medical centers and sanatorium-resort facilities of Ukraine for further use in medical practice; must meet ethical requirements (Teremetskyi *et al.*, 2019).

The last criterion of the specificity of intellectual property objects in the field of medicine is quite debatable, in connection with which it affects the general state of the introduction of innovations in the specified field. Thus, any scientific medical discovery must be accompanied by thorough, in particular, experimental research, as it concerns human life and health.

The Declaration of Helsinki declares that scientific research in the field of biology and medicine is carried out without hindrance, subject to compliance with the provisions of this Convention and other legal provisions that guarantee human protection. Scientific research on humans can be conducted only if there is no alternative, the effectiveness of which would be similar to the effectiveness of research on humans. The risks to which such a person may be exposed must be commensurate with the potential benefit from the research (Kashintseva, 2013).

Thus, for objects of intellectual property in the field of medicine, it is important to maintain a balance between scientific novelty and its significance for treatment and philosophical humanism, which calls on scientists in this field to refrain from reckless research.

The field of health care is also connected with other objects of intellectual property, however, these objects are generally related to the commercialization of this field, so they are not particularly important, in particular, for post-war development. For example, a business entity engaged in the production and distribution of relevant drugs, or an entity engaged in medical practice, may own such intellectual property objects as a commercial (brand) name, a trademark (signs for goods and services), trade secret. The specified objects of intellectual property services distinguish their subjects from other representatives of their type of activity but are not directly related to the main purpose of the existence of the healthcare sector - maintaining the physical and psychological health of society.

In addition, the use of intellectual property in the field of health care can also be divided by purpose:

- 1) objects of intellectual property used in the process of providing direct medical care (such objects were mentioned above), and;
- 2) intellectual property objects used to improve service.

This group of objects can include, for example, various devices, programs, applications, and databases, which will help make the field of health care more understandable and accessible, as well as facilitate the administrative component of providing medical services. Such an object can be, for example:

- the database of patients of the relevant medical institution, which will minimize the need to spend time on re-filling personal data about the patient, his state of health, and the results of previous visits to the institution, and;
- a suitable mobile application for an independent, convenient, and accelerated appointment with a doctor in the relevant institution, obtaining prescriptions for medicines.

A striking example of organizational modernization at the state level in the field of health care is the introduction and mandatory use of the Electronic Health Care System in Ukraine (eHealth) - a two-component system in which the user interacts with the central database through the electronic medical information system. The specified system, in addition to the possibility of obtaining electronic prescriptions for drugs, and choosing a doctor, contributes to the creation of space for innovations in medicine (machine learning, big data, blockchain), which is stated in the main goals of the system (Electronic healthcare system in Ukraine, 2023).

Thus, the state clearly showed its desire for changes in the medical field and demonstrated its interest in it.

The above shows that Ukraine understands the importance of intellectual property, in particular, for the post-war development of the healthcare sector, and aims to encourage it, but it is currently impossible to speak of complete readiness for its effective and active implementation.

Thus, among the main systemic factors that prevent the formation and development of the medical and biotechnological industry of Ukraine, it is possible to single out the lack of a systemic legislative framework that regulates the relevant industries, including a certain imperfection of legislation in the field of intellectual property, which would take into account the specifics of medical and biotechnological objects of intellectual property (Nimko, 2017).

As an example, the Law of Ukraine “On the Protection of Rights to Inventions and Utility Models”, which regulates the legal protection of relevant objects of intellectual property, in accordance with the provisions of Part 3 of Article 6 of the said legislative act, does not apply to surgical or therapeutic methods of treatment of humans or animals, methods of diagnosing the human or animal body. This provision does not apply to products (substances or compositions) used in diagnosis or treatment (Law 3687-XII, 1993).

However, practice shows that methods of treatment are objects of intellectual property and may well fall under the concept of the invention (utility model), therefore they need proper registration and protection, against the background of which there are gaps in the Ukrainian legal

framework, which currently does not cover all needs to ensure the proper level of implementation of some types of intellectual property objects in the field of medicine.

Among the most problematic issues for the healthcare sector are: patent protection terms, utility model and industrial design patent protection, “evergreen” patents, compulsory licensing, and exhaustion of intellectual property rights. These problems create negative phenomena in the form of the unavailability of medicines for the patient (Datsko, 2018).

Thus, within the limits of patent law, the issue of observing the public interest when inventing an invention (useful model) valuable from the point of view of human health is acute. Restrictions on the disposal of property rights to intellectual property objects are the reason for the impossibility of effective widespread use of the corresponding object, which results in irreparable deterioration of human health and even loss of human lives.

Currently, there is still no legal position in Ukraine regarding the limits of the inventor’s right to his invention and the right of an individual to ensure the proper state of health on the part of the state. Thus, due to the lack of priority of public interest, many objects of intellectual property in the field of medicine are sold abroad with the aim of obtaining profit by the subject of copyright or due to the bureaucracy and difficulty of obtaining patents in Ukraine, lack of funding, while Ukrainians are forced to use such objects for significant costs or do not have the opportunity to use them at all.

For example, Ukrainian scientists invented the technology for the production of batulin, which is an antibiotic with a strong effect against staphylococcal infection, but due to the lack of appropriate funding in Ukraine, they were forced to sell such technology to Belgium for interest from the sale of the finished medicinal product on the European market (Ilyashenko, 2014).

A similar situation occurred with the Kharkiv scientist A. Malikhin, who invented a special device for conducting blood analysis of blood sampling bases. The specified device in the form of a sensor is placed on the patient’s neck and stomach and reads the relevant data, which later appear on the computer monitor as 117 indicators of human health, necessary, in particular, for establishing a diagnosis. However, even here Ukrainians did not benefit from this invention, as it is produced by a private company and sold abroad (Ilyashenko, 2014).

Therefore, cases, when Ukrainian patients are forced to pay for the monopolization of treatment and diagnostic methods, are not an exception, which is unprecedented for Europe. At the beginning of the XXI century, the Baltic countries and Georgia faced similar problems. However, they quickly got rid of the philosophy of “absolutization of intellectual property rights”

imposed by the pharmaceutical and medical lobby and speculations about the financial costs of developing a new innovative product (Kashintseva, 2015a).

According to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), member states (signatories of the agreement) can use a significant number of its flexible provisions at their own discretion and decide, in particular, the issue of exclusion from legal protection by patent legislation of diagnostic, therapeutic and surgical methods of treatment. Currently, Ukraine has not used this privilege (Kashintseva, 2015b).

Thus, taking into account that Russia's war with Ukraine activated many internal political reform processes, it is worth addressing the issue of determining priorities between the property rights of intellectual property subjects in the field of health care and the public interest in ensuring the proper level of prevention, diagnosis, and treatment of the population. Just as in copyright in the field of health care, a fair solution to the problem of the inventor's property interest can be compensated for the use of the invention by the state.

The given examples of the leakage of important results of intellectual activity in the field of health care of Ukrainian medical scientists not only demonstrate the losses of Ukrainian society from the imperfect protection of their rights to an adequate level of medicine but also illustrate the unrealized possibility of economic growth of the state at the expense of foreign investments that could have been attracted for the production and distribution of certain object of medical intellectual property.

In the post-war period, more than ever before, Ukraine will need large funds to restore the improvement of temporarily occupied and other affected territories, infrastructure, and compensation for losses of human and housing stock, in connection with which the inflow of capital investments and other investments in Ukrainian products, in particular, created within the sphere of health care, is a necessary condition for the reconstruction of Ukraine and the achievement of its development goals.

An alternative for the effective development, in particular, of the healthcare sector in the post-war period is to also consider the issue of stimulating the creation and development of spin-off companies, in particular university ones.

The experience of the USA confirms that one of the effective mechanisms for identifying and using objects of intellectual property rights, in particular, in the field of biotechnology, is the creation of management structures, such as spin-off companies, which are widely a recognized way of commercializing the results of scientific research (objects of intellectual property rights). These university structures directly enter the market, accordingly, there is a great chance of success for spin-offs (additional

sources of income). The emergence of this new American model and its enormous popularity in the biotechnological sector forces other countries to reconsider the relationship between university science and industry (Korogod and Novorodovska, 2020).

Thus, the activity of such companies is risky, but it will allow expanding the opportunities of universities or other scientific institutions conducting relevant research in the field of medicine, the results of which fall under the characteristics of intellectual property objects, to enter the wide market, that is, to make an object of intellectual property, which has important public importance, more accessible.

## Conclusions

Intellectual property is an important achievement of modern society, which is evidenced by the impossibility of proper development of any sphere of social life without its use since intellectual property is designed not only to ensure the property and non-property interests of the subject of the specified property but is aimed at ensuring the needs of society in general in the appropriate sphere, where objects of intellectual property find their application.

Despite the above, the role of intellectual property objects in the field of health care is currently not sufficiently appreciated, as a result of which there are gaps in the regulation and protection of such objects, an imperfect conceptual apparatus, and a limited worldview regarding their use in practical medicine.

The post-war development of the health care sector should be based on the principles of maximum involvement of the results of intellectual activity in the form of objects of copyright and patent law on issues related to medicine, as well as aimed at ensuring the digitization goals of the state, since only under the condition of such involvement is it possible there will be effective development of the specified area, which in turn will lead to the formation of a physically and morally healthy society, increase in the level of public trust in the government and its social programs, attraction of a significant amount of foreign and domestic investments, improvement of the reputational status of Ukraine at the international level.

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