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PROBLEMS OF BIOTECHNOLOGY LEGAL REGULATION IN THE FIELD OF HEALTHCARE

Introduction. *The process of overcoming the pandemic and the intensification of hostilities have exacerbated the necessity of developing a legal mechanism for the control and use of biotechnology in various fields. The rapid entry of innovation technologies into the medical industry is prompting changes in the entire healthcare sector, from the formation of public policy to the mechanisms for transferring the advanced biotechnologies to medical practice.*

Problem Statement. *The vector of the research is to identify and find ways to address urgent legal gaps in the implementation and transfer of biotechnology in the healthcare sector, as well as to assess the prospects of medical biotechnology as one of key investment areas.*

Purpose. *Legal analysis of the problematic aspects of the development, implementation, and transfer of biotechnology in the field of healthcare for the prevention, diagnosis, and treatment of the most common diseases, study of their impact on the development of personalized medicine, as well as importance for the post-war recovery strategy of Ukraine.*

Material and Methods. *The basis of the research methodology is its anthropological orientation. Methods of synthesis and analysis, empirical, historical, and system-structural methods, as well as forecast and economic and legal analysis methods have been employed.*

Results. *A comprehensive study of the legal regulation of the interdisciplinary area of biotechnology in the medical field to improve the social welfare of the population through the introduction of innovative technologies has been launched. Attention has been focused on the potential and prospects of medical biotechnology in terms of its attractiveness for the investment policy of post-war reconstruction of Ukraine.*

Conclusions. *The research and theoretical framework of medical biotechnology has been developing much faster than the legal mechanism of their introduction into medical practice, which may limit the personal non-property rights of natural persons, which ensure their natural environment. This area is also an effective component of economic and legal development that is a driver of economic opportunities and innovations.*

Keywords: biotechnology, technology transfer, personalized medicine, regulation in the field of biotechnology, biotechnology in the field of healthcare, innovation, post-war recovery.

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The Convention on Human Rights and Biomedicine clearly and unequivocally declares the priority of the interests and well-being of the individual over the interests of society as a whole or science [1]. The rapid integration of innovation technologies into everyday life, including the medical field, obliges us to reconsider, analyze, evaluate, and review the socio-economic, legal, and moral-ethical aspects arising in medical, pharmaceutical, biotechnological, and other sectors of economic activity. It is known that the more rapidly innovation technologies such as cloning, genome editing, personalized therapy, and others develop and are implemented, the more complex become the issues of ensuring biosecurity and the regulative framework for accompanying the use of scientific achievements.

The current stage of development of public consciousness is characterized by a rapid increase in the content and quality of innovation developments that ensure successful growth of the profits of economic entities and the satisfaction of the modern market demand. The titanic shift in socio-economic organization of social relations over the past decades has been a result of the achievements of fundamental research in the field of natural, mathematical, materials science, engineering, and other branches of science, simultaneously with the explosive development of information technology. At the same time, one of the key factors in determining the level of well-being of the population remains the degree of development of the healthcare sector. We all, as direct participants in healthcare relationships, bear a certain responsibility for shaping individual aspects of modern and future models of health preservation and for improving the quality of human life.

Given the COVID-19 pandemic that shook the entire world a few years ago, the risks of biological weapon use, particularly during armed conflicts, as well as the rapid implementation of various innovation technologies, the issue of developing a legal mechanism for controlling and applying biotechnologies of various kinds is extremely relevant. This issue is particularly important in the context of developing a post-war economic recovery strategy for Ukraine, as it is an undeniable fact that has been confirmed by global experience that in advanced economies, high-tech sectors (including the development and implementation of biotechnology) have the largest share in GDP and are economically attractive to potential investors.

Several scholars have actively explored specific legal aspects in the field of biotechnology, including I. I. Bochkova, V. I. Kurylo, M. O. Medvedieva, Yu. O. Piddubnyi, and others. Significant attention has been paid in legal literature to various aspects of regulation and protection of intellectual property rights in biotechnology, which have been actively researched by N. Glushchenko, I. Kuzmich, O. Olefir, O. P. Orliuk, and others. The development and timely implementation of biotechnology hold significant social importance, as they can directly influence the realization of human rights to life and health. Therefore, considerable scholarly attention has been focused on issues of legal regulation of technology transfer. Among these scholars, there are O. Bakalinska, O. M. Davidyuk, V. S. Dmytryshyn, Yu. M. Kapitsa, O. P. Kosenko, A. A. Mazaraki, Ye. A. Novikov, D. I. Pohribnyi, L. I. Fedulova, and others.

In her dissertation, M.O. Medvedieva has emphasized the importance of sticking to legal standards in the implementation of biotechnology in agriculture (cultivation of genetically modified animals and plants with qualitatively new characteristics); medicine (cell technologies, genetic engineering, creation of recombinant pharmaceuticals, cloning); biological weapons [2, p. 25]. Despite numerical studies on various aspects in the field of biotechnology, currently, there has been a lack of comprehensive analysis of the legal regulation of the development, implementation, and transfer of biotechnology in healthcare. This issue is particularly relevant in the nascent stage of personalized medicine. From standpoint of business activity and implementation prospects, the entities engaged in entrepreneurial activities in the healthcare sector are particularly interested in the potential application of stem cells and genome editing.

It is worth noting the role of biotechnology in oncology. The deciphering of the human genome and the development of genomics have allowed obtaining information about the correlation of certain proteomic abnormalities with the probability of developing specific diseases [3, 8].

The purpose of this research is to analyze the legal aspects of the development, implementation, and transfer of biotechnology in healthcare for the prevention, diagnosis, and treatment of the most prevalent diseases, as well as their significance for the post-war recovery strategy of Ukraine.

Ukraine's legislation defines the term "technology" as the result of R&D activity, a set of systematized scientific knowledge, technical, organizational, and other decisions regarding the list, terms, order, and sequence of operations, the process of production and/or realization, and storage of products, provision of services [4]. Analyzing this concept, V. S. Dmytryshyn has reasonably noted [5, p. 85] that "technology" is a complex legal phenomenon that contains and organically combines both intellectual property rights with various legal regimes and rights to information, data, knowledge, and experience, organizational and economic decisions, sequence of actions and processes, as well as other diverse elements. For further uniform understanding of the concept of "biotechnology," it is worth referring to its legal definition. According to the provisions of Article 2 of the Convention on Biological Diversity of 1992, biotechnology is defined as any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use [6]. Thus, biotechnology in the field of healthcare can be considered a technology that combines various elements simultaneously or separately: intellectual property rights, a certain system of actions and processes, organizational and economic decisions, valuable products, etc., particularly to meet the needs arising in the healthcare sector (medical, pharmaceutical, or other related industries).

The advanced development of biotechnology will accelerate the implementation of tools designed for the needs of personalized medicine. These fields are directly interconnected because innovation products for clinical medicine enable significant progress in healthcare, ensuring not only diagnosis and treatment tailored to individual patient characteristics but also timely prevention of certain diseases or their complications. Modern principles of personalized medicine are based on identifying the molecular-genetic characteristics of specific parameters and the epigenetic profile of every patient, which can influence selecting drugs or treatment protocols, minimizing side effects or ensuring more successful outcomes. Personalized medicine can also indicate individual's predisposition to certain diseases, allowing doctors and patients to develop an individualized monitoring and prevention plan [7, p. 8].

In his research, Steve Sturdy [9, p. 31] has considered personalized medicine a branch of the medical biotechnology sector, which has its roots back to the 1980s when the biotechnology industry began to emerge as a new form of scientific activity characterized by an unprecedented interpenetration between academic and commercial institutional forms and blurring of the old distinctions between fundamental science and market-oriented research and development. From this, it can be concluded that the promise of commercial gain was a driving force for the flourishing of biotechnology, which was entirely predictable in the conditions of a market economy.

At the same time, regulatory policy in the field of biotechnology is complicated by the complexity of the industry itself, as it combines both innovation development activities in general and activities within the healthcare system. The latter includes a range of directions such as the development of treatment and/or prevention methods, pharmaceutical production, research that involves biobanks, the implementation of systems using artificial intelligence elements, and so on. Each direction has specific features both in practical application and in terms of government regulation. Considering that a significant portion of biotechnology results from the activities of speciali-

zed research institutions or relevant departments of educational institutions, one of the final stages of biotechnology implementation is the process of technology transfer or commercialization. This process often serves as an element of regulatory policy responsible for transforming biotechnology into an economically viable product. As noted by S. Tsivkach in the *United 24* Economic Strategy for Post-War Recovery of Ukraine, one of the mechanisms for financing Ukraine's reconstruction needs by Western countries is technology transfer. It may involve venture capital that is more widespread in the United States than in Europe. Improving the situation with technology transfer in Ukraine could be facilitated by the creation of technological clusters, where Ukraine could demonstrate better results and create additional benefits for the world in areas such as biotechnology, MedTech, blockchain, cybersecurity, and more [10].

The theoretical and legal aspects of technology transfer, its distinction from the process of commercialization, have been thoroughly studied by Ye. A. Novikov. The scholar has stated that there are the two main concepts defining technology transfer in relation to its commercialization process: the unity theory and the independence theory. The legal significance of establishing terminological connections between the concepts of "technology transfer" and "technology commercialization" lies in the sphere of legislative regulation and the formation of economic legal policy [11, p. 45]. Among numerous approaches to defining these concepts, several are noteworthy. According to A. V. Kosenko, the commercialization of intellectual property objects is an independent process of transforming the results of R&D and innovative activities into goods and effectively realizing them on an industrial scale [12, p. 35]. O. M. Davidyuk has proposed the most comprehensive definition of technology transfer as authorized actions performed by an economic entity or other party in relations related to the creation, transfer of rights, and embodiment of technologies, organizational and economic actions, or the conclusion of the relevant economic or civil contracts, and/or the performance of other legal acts or organizational and managerial actions of a public law nature aimed at transferring rights to technology, or information about technology, and/or material embodiment (reproduction) of technology from one subject (party) of these relations to other, with the purpose of their further transfer to other subjects or use for organizing production activities (commercialization) [13, p. 33].

Technology transfer or commercialization may have various economic and legal forms, which is an extensive problem deserving separate research. However, it is worth noting that the most significant results in the field of medical biotechnology can be achieved within the framework of public-private partnerships [14]. The most famous example is the Human Genome Project, which was realized through joint efforts of the public and private sectors and resulted in sequencing the entire human genome two years ahead of schedule in 2003, after 13 years of work. Other examples of joint public-private research programs include the International HapMap Project, which helps researchers identify the genetic causes of diseases and responses to drugs, and the Cancer Genome Anatomy Project that provides open access to genetic information related to cancer [15, p. 141].

As a candidate country for EU accession, Ukraine should align its policies with those of EU member states, many of which have developed robust government programs aimed at developing and commercializing technology infrastructure, including biotechnology. These programs involve strategies for initiating and developing businesses, building strategic partnerships, protecting intellectual property rights, marketing, licensing, venture financing, and investing in companies, identifying opportunities for further technology development [16, p. 64], and utilizing them considering both public and private interests. However, while aligning with the European values and standards and analyzing the largest biotechnology market in the US, it is important to keep in mind that countries such as China, India, and Brazil are expected to play an increasingly signi-

ficant role in the future R&D market in biotechnology. This includes buying intelligence, including from Ukraine. This risk should be properly considered and assessed when forming government regulatory policies regarding the development, transfer, and use of biotechnology.

The current task facing the state is to build Ukraine as a worthy member of the European and global community through progressive innovation, investment, trade, and industrial policies [17, p. 86]. This direction will elevate Ukraine's post-war status, including on the international stage, attract significant investments, and preserve and enhance the country's R&D potential that is key to further prosperity and competitiveness. For example, O. Borodina and V. Lyashenko [18, pp. 128—129], while analyzing a series of effective post-war development cases in national economies, draw attention to the model of the Irish innovation offshore, which serves as an acceptable example for borrowing and implementing in post-war Ukraine. The researchers have noted that in 1990, the economic indicators of Ukraine and Ireland were comparable (GDP per capita based on PPP was USD 16,000, in Ukraine, and USD 22,000, in Ireland). However, over the next 30 years, Ireland has become one of the richest countries in Europe, while Ukraine has been among the poorest ones. Ireland's prosperity is facilitated by the tax reform that has transformed Ireland into a corporate tax haven, with effective tax rates for foreign corporations ranging from 2.2% to 4.5%. Additionally, Ireland's industrial structure demonstrates the dominance of high-tech industries, with the biotechnology and pharmaceutical sector having the largest share of total sales in 2019. This case is a vivid confirmation of the economic significance and the potential for development in the biotechnology sector, which should not be ignored.

Analyzing the system of international legal order in the field of biotechnology, it can be stated that in the era of globalization, civilized countries adhere to certain elements of contemporary integration processes, including harmonization, unification, and convergence of law [19, p. 141]. However, as noted by O. Bakalinska [20, p. 116], the implementation of European directives and regulations into the Ukrainian legislation is not a guarantee of the development of conscientious and transparent technological exchange and technology transfer.

Given the above, as well as in the context of planning the strategy for post-war reconstruction of Ukraine, the regulatory environment for activating domestic biotechnological progress is of paramount importance. This encompasses various elements of regulatory frameworks, government regulatory policies, and self-regulation within the conditions of a market economy. The predictability of regulatory policies influences the directions, types, pace, costs of biotechnological research, and the potential for their implementation, as well the determination of the degree of their commercial viability. Regarding the application of biotechnology in healthcare, technical developments and high research costs create a set of regulatory challenges, namely the need to balance risks and benefits with the costs of developing various treatment modalities. The regulatory experience in the development, production, and distribution of pharmaceuticals, accumulated over a long period, has shown that the balance of risks and benefits may change significantly with R&D advancements and experience, which necessitates adjustments to healthcare system rules [21].

In the healthcare sector, the future of regulatory policy is not sufficiently clear and straightforward, as economic pressures and technical capabilities push it in different directions. Intellectual property rights have been increasingly being used to incentivize knowledge exchange through cooperation mechanisms such as patent pools or research consortia. Societal attitudes towards biotechnology will continue to influence market opportunities, but public opinion may change, especially when biotechnological products bring significant benefits to consumers or the environment [15, p. 137]. From an economic perspective, the diffusion (including transfer) of technologies not only leads to increasing profit, but also gene-

rates new investments, technologies, jobs, and tax revenues to the budget, directly linked to the growth of the country's prosperity [22, p. 76].

The full satisfaction of the population's needs in the state is possible through the timely formation and enrichment of the regulatory framework by improving the existing and developing new legislative one. For example, the finalization of the Law of Ukraine on the Application of Transplantation of Anatomical Materials to Humans towards the development of bio-implants (medical products made from human anatomical materials) and the adoption of a new law of Ukraine on Medicinal Products open opportunities and confidence in combating tumor disease. An example of this is the original technology developed by the R.E. Kavetsky Institute of Experimental Pathology, Oncology, and Radiobiology of the NAS of Ukraine for the manufacture of anti-tumor vaccines from tumor tissue of patients by modifying tumor antigens with lectins *B. subtilis* B-7025. Comprehensive treatment of cancer patients using the IEPOR NASU Antitumor Vaccine increases treatment efficiency and overall patient survival by 15—30%, extends the average lifetime, and improves the quality of life [25, p. 74—75]. Industrial technological regulations (No. TPR 64-37046921-001-05 dated February 21, 2006, protocol No. 8) for the production of antitumor autovaccine have been developed by the Institute and approved by the State Service of Medicines and Medical Devices of the Ministry of Healthcare of Ukraine. The full-cycle preclinical and three phases of clinical trials have been conducted, and certificate of state registration of the medical immunobiological product *Antitumor Autovaccine* (No. 411/03-300 200000 dated December 9, 2003) has been obtained.

The methods for manufacture of the anti-tumor vaccine and treatment using it have been protected by 25 patents of Ukraine. To introduce the IEPOR NASU Antitumor Vaccine into clinical practice, 2 methodological recommendations and 7 information sheets have been prepared. The work is awarded the State Prize in 2016. However, the Institute has failed to re-register the vaccine, because of the absence of a license for its production. However, it is necessary to note that according to the technology and recommendations of oncology specialists, the vaccine is manufactured in the Institute in laboratory conditions individually for each patient and fully complies with the requirements of modern oncology for personalized treatment of cancer patients. According to the Licensing Conditions for Economic Activities in the Production of Medicines, Wholesale and Retail Trade in Medicines, Import of Medicines (except for active pharmaceutical ingredients), such a license cannot be obtained, as the relevant activity is not related to the mass production of medicines and is exclusively individual.

Thus, there is a legal gap, and despite having developed biotechnology and necessary production resources, the economic entity is deprived of the opportunity to widely apply antitumor autovaccine, and patients are deprived of a chance for survival because of the circumstances outlined. Such regulatory gaps narrow a range of patient rights, including the right to individualized treatment, qualified medical assistance, accessibility in healthcare, freedom of choice in healthcare, quality medical care, innovations, prevention of suffering and pain, and so on.

At the same time, Article 3 of the Law of Ukraine on Medicinal Products dated July 28, 2022, declaratively defines support for the field of scholarly research, creation, and implementation of advanced technologies to provide patients with access to innovation treatment methods as one of the fundamental principles of state policy regarding ensuring the effectiveness, quality, and safety of medicinal products. However, the scope of this law does not extend to medicinal products based on any type of human or animal cells. So, despite the pharmacological similarity of antitumor autovaccine to a medicinal product, the legal nature of such a vaccine should be considered in the context of transplantation legislation, although the Law of Ukraine on the Application of Transplantation of Anatomical Materials to Humans does

not extend to the manufacture of bio-implants and xenoimplants, although it regulates many aspects related to their use, extraction procedures, and so on. The more detailed procedure for the manufacture, quality control, and circulation of bio-implants is approved by the Resolution of the Cabinet of Ministers of Ukraine dated February 24, 2021, № 158, on Some Issues of Implementing the Law of Ukraine on the Application of Transplantation of Anatomical Materials to Humans regarding bio-implants, xenotransplants, medical-biological requirements for animals, conditions of their maintenance, procedure for the extraction of anatomical materials from animals for the manufacture of xenotransplants [26]. This general procedure, despite its progressiveness, leaves more questions than gives answers, particularly regarding clinical trials of bio-implants. However, it serves as a significant regulatory framework for further development of the field.

In the context of the outlined case, the issues regarding the commercialization of biomedical developments or technology transfer have repeatedly arisen. In recent research in the biomedical field, it has been noted that since the antitumor autovaccine is an innovation development, first mastered in the country and possessing qualitatively new techno-economic indicators, revenues from the use of the technology are generated by intellectual property objects underlying it [27, p. 201].

Improving the regulatory legislation, particularly in the field of biotechnology, or forming new legal mechanisms, as in the case of updating the transplantation and pharmaceutical legislation, will help avoid similar legal problems regarding the further implementation and/or transfer of technology. For a long time, access to this technology has been limited for oncology patients in the domestic market, which is related to gaps in legislation. The manufacture of such autovaccine does not fall under the category of "manufacture of medicinal products" since this product is an individual one that uses anatomical materials of a specific patient, unlike the serial medical products that are regulated by the applicable law, and there has been no other legal concept in legislation. This practical case vividly demonstrates the several important aspects:

1. The period from the moment when a certain biotechnology is developed and its effectiveness is proven until its implementation takes from several years to decades.

2. The R&D progresses at a much faster rate than the regulatory frameworks are updated, which can significantly slow down the entry of biotechnologies into the market and access for broad segments of the population to the latest achievements.

3. The sphere of innovation that includes the process of biotechnology development and the manufacture of antitumor vaccines, is significantly stalled, providing competitors with the opportunity to capture not only the global but also the domestic market for individual biotechnological products.

In the given context and as a result of the analysis of global experience, we have concluded that the triple helix concept based on the close cooperation of government bodies, research institutions, and commercial enterprises deserves attention. Such a model has been studied by A.V. Zelisko and O.V. Rozgon, who consider the regulation of the legal status of subjects of innovation. Thus, they have projected a corresponding model onto scientific parks, paying attention to the increased requirements for their creation and operation, as well as the level of state control over them. At the same time, it should be noted that the sphere of innovation that includes the development, implementation, and market realization of biotechnological products, is not limited to activities within scientific or technological parks. The aspect of interaction between various subjects and scientific and educational institutions remains important and attracts significant attention from the state. However, as it has been established by the assessment of the scientific orientation of legislation, the R&D development of the country remains at a secondary level, resulting in a persistent crisis in the regulation of science since 1992 [29, p. 45].

Summarizing the overview of this complex issue, it is worth agreeing with the results of the forecast analysis regarding the development of the bioeconomy by 2030, by the Organization for Economic Cooperation and Development, where it has been noted that the development of biotechnology is influenced by the three institutional driving forces and one social driver, namely: government support for biotechnological research and continuous training of researchers, regulatory framework, intellectual property, and societal recognition.

Thus, the cited study has established that the scientific and theoretical basis of medical biotechnology is developing at a much faster pace than the legal mechanism for its implementation in medical practice, which may limit the personal non-property rights of individuals, which ensure their natural existence (rights to life, healthcare, medical aid, etc.). In addition to the social effect for consumers from the implementation of such innovation technologies, the goal is also to obtain economic opportunities and benefits that may manifest themselves not only in the form of profit but also in reducing the cost of treatment, increasing its effectiveness, or improving the survival rate and quality of life of patients. Biotechnology in healthcare is the key and foundation for the development of personalized medicine both in Ukraine and worldwide. The legal model of personalized medicine should take into account the elements of innovation and flexibility of this direction, which entails a review of the rather conservative healthcare system.

The highlighted issues regarding the legal regulation of biotechnology in healthcare in general, and personalized medicine in particular, demonstrate the complexity of the matter that covers all aspects of economic relations, from production to organizational and administrative and economic ones. The medical biotechnology is developing within the framework of a general innovation system, the structural elements of which include as follows: government regulatory policy; education and science; appropriate infrastructure; model of practical implementation; and innovation environment. Despite the complexity of Ukraine's legislation, there remain several issues for investigation, including the finalization of the legal mechanism for government support not only during the research stage but also for financial incentives for the preparation, production, distribution, and implementation of biotechnology in healthcare. There are several obstacles during its implementation because of the fact that biotechnology is usually the result of innovation, while the high degree of justified regulatory constraints in regulating economic activity in the fields of medical practice, production and distribution of pharmaceuticals, and related activities becomes a constraining factor. Overcoming such obstacles will expand the scope of medical tourism and, thanks to biotechnology will open up the medical market of Ukraine to patients from around the world not only in terms of affordability but also due to the high quality and innovativeness of services.

Particular attention should be paid to the planning of post-war reconstruction strategy in Ukraine. Until the basic hospital services and infrastructure are restored, medical biotechnology remains within the context of scholarly research activity at the level of self-financing. However, it is already necessary to develop a working mechanism for capitalizing on the existing potential, particularly by optimizing tax legislation to create an investment-friendly climate for attracting additional funding into such high-tech industries. Currently, the only successful formula for technological development is close cooperation between the state (including specialized government agencies), academia (or relevant departments of educational institutions), and business, as well as international cooperation. The potential of this direction has been evidenced by implemented global public-private biotechnology projects that have enabled significant progress in healthcare.

REFERENCES

1. Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine: Convention of Council of Europe of 04.04.1997. URL: https://zakon.rada.gov.ua/laws/show/994_334#Text (Last accessed: 01.03.2023).
2. Medvedieva, M. O. (2005). International legal standards of state cooperation in the field of biotechnology. (PhD) (Law). Kyiv [in Ukrainian].
3. Pereginya, O. V., Lutsenko, T. M. (2020). Translation medicine, biomedicine and medical biotechnology: the transition to personalized medicine. *Biotechnologia Acta*, 13(2), 5—11. https://doi.org/10.15407/biotech13.02.005.
4. On State Regulation of Activity in the Sphere of Transfer of Technologies: Law of Ukraine of 14.09.2006 No. 143-V. Voice of Ukraine. 2006. 14 November. (No. 213). P. 10—22.
5. Dmytryshyn, V. S. (2021). Regarding the subject and the object of the technology transfer agreement. *Research Papers of National University "Odessa Law Academy"*, 29, 85—91. https://doi.org/10.32837/npnuola.v28i29.719 [in Ukrainian].
6. Convention on Biological Diversity of 05.06.1992. URL: https://zakon.rada.gov.ua/laws/show/995_030#Text (Last accessed: 01.03.2023).
7. Vogenberg, F. R., Barash, C. I., Pursel, M. (2010). Personalized Medicine. Part 1: Evolution and Development into Theranostics. *Pharmacy and Therapeutics*, 35(10), 60—67.
8. Chekhun, V. F. (2019). MicroRNAs are a key factor in the globalization of tumor-host relationships. *Exp. Oncol.,* 41, 188—194. https://doi.org/10.32471/exp-oncology.2312-8852.vol-41-no-3.13431.
9. Sturdy, S. (2017). Personalised Medicine and the Economy of Biotechnological Promise. *The New Bioethics,* 23(1), 30—37. https://doi.org/10.1080/20502877.2017.1314892.
10. Serhii Tsivkach: "The most important thing in wartime is to maintain existing businesses" (2022). URL: https://gmk.center/ua/interview/sergij-civkach-najvazhlivishim-u-voiennij-chas-ie-pidtrimka-isnujuchogo-biznesu/ (Last accessed: 01.03.2023) [in Ukrainian].
11. Novikov, Ye. A. (2019). *Legal regulation of the activity of technology transfer networks*: monograph. Kharkiv [in Ukrainian].
12. Kosenko, A. V. (2009). Organizationally economic mechanism of commercialization intellectual property objects of enterprises. (PhD) (Econom.). Kharkiv [in Ukrainian].
13. Davydiuk, O. M. (2021). Problems of identification of the concept of technology transfer: economic and legal aspect. *Law and Innovation Society*, 1(16), 31—36. https://doi.org/10.37772/2309-9275-2021-1(16)-4.
14. Ustymenko, V., Rossylna, O. (2022). The role of public-private partnership in optimization of healthcare sphere (on the example of personalized medicine): risks and prospects. *Law Journal of Donbass*, 4(81), 2, 45—51. https://doi.org/10.32782/2523-4269-2022-81-4-2-45-51 [in Ukrainian].
15. The Bioeconomy to 2030. Designing a policy agenda. OECD publishing. 2009. 326 p. URL: http://www.sourceoecd.org/generaleconomics/9789264038530 (Last accessed: 01.03.2023).
16. Hruzdova, T. V., Yukhnovska, T. M. (2014). Prospects for development of pharmaceutics and biotechnology with ukraine's accession to the association agreement with the European Union. *Ukrainian Society*, 3(50), 63—77 [in Ukrainian].
17. Krekhivskyi, O., Salikhova, O. (2022). Povojenna modernizacija promyslovosti: vnutrishni ta zovnishni resursy. *Foreign trade: economics, finance, law*, 6, 83—104. https://doi.org/10.31617/3.2022(125)06 [in Ukrainian].
18. Borodina, O. A., Lyashenko, V. I. (2022). Post-War Economic Recovery: World Experience and Attempt to Adapt it for Ukraine. *Herald of the Economic Sciences of Ukraine*, 1(42), 121—134. https://doi.org/10.37405/1729-7206.2022.1(42).121-134 [in Ukrainian].
19. Zhylina, O. V. (2019). Modern biotechnology and legal regulation of their use in the context of globalization. *Odesa National University Herald. Jurisprudence*, 24, 2(35), 136—142. https://doi.org/10.18524/2304-1587.2019.2(35).186666 [in Ukrainian].
20. Bakalinska, O. (2022). International transfer of technologies in the conditions of modern challenges. *Theory and Practice of Intellectual Property*, 4, 109—120. https://doi.org/10.33731/42022.265926 [in Ukrainian].
21. Dukes, M. N. G. (2008). Biotechnology Regulation in the Health Sector. URL: www.oecd.org/dataoecd/11/14/40926707.pdf (Last accessed: 01.03.2023).
22. Prokhorova, V., Bozhanova, O., Hrytsyna, O. (2019). Transfer of technology as a component of innovative development of enterprises. *Agrarian Economy*, 12(3—4), 71—76. https://doi.org/10.31734/agrarecon2019.03.071 [in Ukrainian].
23. On the application of transplantation of anatomical materials to humans: Law of Ukraine of 17.05.2018 No. 2427-VIII. URL: https://zakon.rada.gov.ua/laws/show/2427-19#Text (Last accessed: 01.03.2023) [in Ukrainian].
24. On Medicinal Products: Law of Ukraine of 28.07.2022 No. 2469-IX. URL: https://zakon.rada.gov.ua/laws/show/2469-20#Text (Last accessed: 01.03.2023) [in Ukrainian].

25. Potebnia, H. P., Lisovenko, H. S., Chekhun, V. F. (2009). Application of cancer vaccines of IEPOR series into clinical practice of oncological establishments of Ukraine. *Sci. innov.*, 5(1), 62—79 [in Ukrainian].
26. Some issues of implementation of the Law of Ukraine "On the Application of Transplantation of Anatomic Materials to Humans" regarding bio-implants, xeno-implants, medical and biological requirements for animals, conditions of their keeping, the procedure for removing anatomical materials from animals for the manufacture of xeno-implants: Resolution of the Cabinet of Ministers of Ukraine of 24.02.2021 No. 158. URL: https://www.kmu.gov.ua/npas/deyaki-pitannya-realizaciyi-zakonu-ukrayini-pro-zastosuvannya-transplantaciyi-anatomichnih-materialiv-lyudini-i240221-158 (Last accessed: 01.03.2023) [in Ukrainian].
27. Piatchanina, T. V. Klochenok, L. V., Tsiukalo, D. V., Dvorshchenko, O. S., Melnyk-Melnykov, P. H. (2022). Peculiarities of using the revenue approach for evaluating intellectual property objects in the biomedical field. *Oncology*, 24(3), 197—202. https://doi.org/10.32471/oncology.2663-7928.t-24-3-2022-g.10795 [in Ukrainian].
28. Zelisko, A. V., Rozghon, O. V. (2022). The Corporate Form of Innovating Entities in Ukraine. *Sci. innov.,* 18(5), 95—108. https://doi.org/10.15407/scine18.05.095.
29. Bublyk, S. H., Bulkin, I. O., Mekh, O. A. (2020). Scientometric evaluation of science-centric orientation of the national legislation. *Sci. innov.*, 16(1), 33—47. https://doi.org/10.15407/scin16.01.033 [in Ukrainian].

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ПРОБЛЕМИ ПРАВОВОГО РЕГУЛЮВАННЯ БІОТЕХНОЛОГІЙ У ГАЛУЗІ ОХОРОНИ ЗДОРОВ'Я

Вступ. Процес подолання пандемії та активізація військових дій загострили питання розробки правового механізму контролю та застосування біотехнологій різного спрямування. Стрімке входження інноваційних технологій у медичну галузь спонукають до змін всю галузь охорони здоров'я — від формування державної політики до механізмів трансферу новітніх біотехнологій у медичну практику.

Проблематика. Вектором дослідження є ідентифікація та пошук шляхів вирішення нагальних юридичних прогалин щодо впровадження та трансферу біотехнологій у галузі охорони здоров'я, а також оцінка перспектив напрямку медичних біотехнологій як одного з ключових інвестиційних напрямків.

Мета. Правовий аналіз проблемних аспектів розробки, реалізації та передачі біотехнологій у галузі охорони здоров'я задля профілактики, діагностики та лікування найбільш поширених захворювань, дослідження їхнього впливу на розвиток персоналізованої медицини, а також значення для стратегії повоєнного відновлення України.

Матеріали й методи. Основою методології дослідження є його антропологічна спрямованість; застосовано методи синтезу та аналізу, емпіричний, історичний та системно-структурний методи, а також методи прогнозування та економіко-правового аналізу.

Результати. Започатковано комплексне дослідження правового регулювання міждисциплінарного напрямку біотехнологій у медичній галузі для підвищення соціального благополуччя населення шляхом впровадження інноваційних технологій. Закцентовано увагу на потенціалі та перспективах медичних біотехнологій щодо привабливості для інвестиційної політики післявоєнного відновлення України.

Висновки. Науково-теоретична основа медичних біотехнологій розвивається значно швидшими темпами, ніж правовий механізм їх впровадження у медичну практику, що може обмежувати особисті немайнові права фізичних осіб, які забезпечують їхнє природне існування. Така сфера також є ефективною складовою економіко-правового піднесення, що слугує драйвером економічних можливостей та інновацій.

Ключові слова: біотехнології, трансфер технологій, персоналізована медицина, регулювання у сфері біотехнологій, біотехнології у сфері охорони здоров'я, інновації, повоєнне відновлення.