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Guaranteeing biological safety as a basis for limiting the patent-protected rights of intellectual property subjects

Oleksii Piddubny*
Doctor of Law, Professor
National University of Life and Environmental Sciences of Ukraine
03041, 15 Heroiv Oborony Str., Kyiv, Ukraine
https://orcid.org/0000-0003-4867-4613

Maryna Deineha
Doctor of Law, Associate Professor
National University of Life and Environmental Sciences of Ukraine
03041, 15 Heroiv Oborony Str., Kyiv, Ukraine
https://orcid.org/0000-0002-4785-7509

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Abstract

The relevance of the subject under study is conditioned upon the rapid and active development of the biotechnological area. This segment of the economy and science requires not only comprehensive preliminary work, but also further legal protection of the interests of inventors and society. The development of biotechnologies regulates not only the present, but also the prospects for the future. But it is important to harmonize the use of biological processes to avoid a biological catastrophe. The purpose of this study was to investigate the possible legal instruments for limiting the patent-protected powers of subjects of intellectual property law to guarantee biological safety. The following methods were used to collect, process, and present information in this paper: general scientific (formal-logical, analysis and synthesis, comparison, induction and deduction, systematization) and special-

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*Corresponding author

legal methods (formal-legal, comparative-legal). This study considered the possibility of limiting the rights granted to the subjects of patenting to guarantee biological safety. International and Ukrainian legislation was analysed in the aspect of patenting biotechnological achievements, compulsory patenting and restrictions on the rights of patenting subjects. The legal nature of biotechnologies as objects of intellectual property rights was identified. Legal measures to restrict the patent-protected powers of subjects of intellectual property rights were highlighted. Attention was drawn to the legal consolidation of the resolution of controversial issues in the field of patenting of biotechnological inventions according to the criteria of ethics and morality. The need to improve the national legislation governing issues of biotechnological research considering the principle of sustainable development, according to which social and ecological aspects should be recognized as a priority, was substantiated. The importance of this study is reinforced by the increased demand for biotechnologies, which leads to certain legal actions related to their protection. The present paper will be useful for scientists in the field of law, medicine, and bioengineering

Keywords: biotechnology; intellectual law; bioresources; patent law; limitation of rights

Introduction

In modern realities, biotechnologies leave the purely scientific sphere and play an important role in the everyday life of a person. The latest research covers increasingly more industries and continues to diversify. Genetic engineering generates crops by applying genetic modification. Notably, biotechnology is an important tool for ensuring that there are enough products intended for nutrition. It is worth paying attention to the emergence of the latest methods of treatment, where embryonic tissues and stem cells are produced through exposure to the human genome. Hence, the interest in the possibility of improving the animal genome and even human cloning. But it is worth realizing the fine line between the perception of biotechnology as a "panacea" for humanity and a destructive force, the use of which can lead to irreversible consequences. Therefore, this study highlights the issue of opportunities to limit the rights of the subjects of patenting biotechnological inventions to satisfy public and individual interests. This issue was raised in the works of scientists – representatives of various branches of science. For instance, I.I. Kuzmich (2019) investigated and evaluated the legal approach to regulating the creation of an intellectual field to ensure the mechanism of civil protection of rights to biotechnologies. A. Barragán-Ocaña *et al*. (2020) covers the issue of the use of all assets of biotechnology in various fields of social activity, namely in therapy, processes of increasing immunity, agriculture, production of consumer and non-consumer products, etc. T.N. Kharatian (2018) highlighted the problem of correlation between ethical norms and the impact of biotechnologies on the fundamental human right – the right to life; specifically, the author investigated the prospects for the development of legal regulation of this issue against the background of the practices of foreign countries. H. Xia and Z. Yuan (2022) focused on the characterization of highly protected objects (biological agents) and their role in global biosafety. The authors point out that scientific research on such objects should be transparent and not cause

any potential threats to biosafety. T.V. Komarova (2020) analysed trends in the development of intellectual property rights in the field of bioengineering. The scientist is engaged in research in areas where it is forbidden to patent the results of medical research and, as a result, there is no legal protection for such biotechnological inventions. N.O. Petrova *et al*. (2017) investigated biosafety issues related to food safety. Scientists present ways to improve national legislation according to EU requirements in the field of food safety.

Despite a considerable number of studies in the field of biological safety, including publications by representatives of various sciences, the problems of legal regulation of intellectual property in the field of biotechnological achievements are still understudied. In this regard, the purpose of this study was to cover the biotechnology as an object of intellectual property law, as well as to analyse the legal principles of restrictions on the rights of patenting subjects in the field of biotechnology to guarantee biological safety.

Materials and Methods

To properly process a considerable number of materials and sources, the authors used the following general scientific methods: the method of analysis and synthesis, induction and deduction, abstraction, concretization, and analogy. Such intersectoral techniques and tools help organize information for further presentation. The statistical method of research, which refers to special scientific methods, is used during the collection, processing, and establishment of certain patterns in the material. An important role is played by special legal methods, such as comparative law and the method of interpretation of legal norms, through which the article is supplemented with legal definitions and the content of legal norms in the field of intellectual rights protection is clarified.

When collecting information for the preparation of a scientific article, the authors used both Ukrainian literary resources and foreign ones. The materials included not only scientific achievements of Ukrainian scientists, but also scientific articles in foreign branch publications. During the study, international and European documents regulating the implementation of intellectual property rights were analysed, namely: Paris Convention for the Protection of Industrial Property (1883), Agreement on Trade-Related Aspects of Intellectual Property Rights (1994), Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (1998), as well as regulations of national legislation on the violated issues: Civil Code of Ukraine (2003), Law of Ukraine "On Protection of Rights to Industrial Designs" (1993), Law of Ukraine "On Medicines" (1996), Resolution of the Cabinet of Ministers of Ukraine "On Approval of the Procedure for Granting by the Cabinet of Ministers of Ukraine a Permit for the Use of a Patented Invention (Utility Model) Related to a Medicinal Product" (2013). The authors also used the materials of court practice on the subject under study.

Results and Discussion

Biotechnology as an object of intellectual property rights

Modern trends of globalization and the processes of European integration of Ukraine necessitate the creation of an effective mechanism of legal regulation of intellectual property rights in the field of biotechnology (Fedotova & Fyl, 2021), conditioned by constitutional provisions, according to which human life and health are the highest value in the state. Biotechnology is one of the priorities in the development of the economy of the world's leading countries (Poliakova *et al*., 2019). Biotechnology is included in the list of advanced

production technologies of the European Union, the United States, and China, and is also an integral component of the most promising components of convergent technologies for international business (Poliakova & Shlykova, 2017).

As a science, biotechnology involves the creation and practical application of living and non-living systems of biological origin in the technological sphere, with the aim of industrial use of the characteristics of microorganisms, cell cultures and subcellular components in the manufacture of agricultural products and the provision of medical services, and therefore it is classified as one of the key industries of the 21st century (Kuzmych, 2019). Regulatory consolidation of the term "biotechnology", which is used in the Convention on Biological Diversity (1992) as "any type of technology related to the use of biological systems, living organisms or their derivatives for the creation or improvement of products or processes for their further use", refers biotechnology to objects of intellectual property law. But an innovative, cutting-edge, or brilliant discovery will not refute the fact that the laws of nature, its phenomena, or abstract ideas go far beyond patent protection. Although biotechnology has demonstrated unprecedented progress, it is also true that the design of bioprocesses must be oriented towards sustainability criteria, where social impact must be a priority. It is necessary to give comprehensive attention to all aspects to guarantee the successful development of future biotechnology programs in the interests of economic development, environmental protection and social security of the country (Barragán-Ocaña *et al*., 2020).

The fundamental constitutional norm, which regulates the right of each subject "to own, use and dispose of their property, the results of their intellectual and creative activity" (Constitution of Ukraine, 1996), gives a clear understanding that biotechnology is the result of the specified activity, and therefore is the object of intellectual property rights. Therefore, such products undoubtedly require legal security and protection.

The specific feature of the legal protection of biotechnology is revealed in the fact that patenting is not a mandatory element of biotechnology, since biotechnology can consist of several objects of intellectual property, which will be presented in materialized and intangible forms (biological material separated from its environment by a certain technological process; a product containing biological material; biological mechanisms of creation, processing of such material, etc.) (Komarova, 2020).

Patent law itself enables the inventor to exclusively use the result of their intellectual activity for a certain period of time and opens access to a technical achievement to a wide range of people. That is, patents for inventions, which include biotechnology, grant their owners a monopoly right to use such technologies under patent protection (Petrova *et al*., 2017). Accordingly, a patent is a document that certifies authorship and rights to biotechnology and the exclusive right to use it within a specified period.

Furthermore, the conditions for obtaining a patent for biotechnological inventions differ from the conditions for patenting in other areas, considering that all inventions in the field of biotechnology are directly or indirectly a product of nature (Andreychenko *et al*., 2020).

According to the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" (1993), legal protection of an invention is provided under conditions, if it "does not contradict public order, generally recognized principles of morality and meets the conditions of patentability". Therewith, compliance with the conditions of patentability means that an invention (utility

model), including biotechnology, must be characterized by originality, have an inventive level and be industrially applicable. And the definition of an invention (utility model) as a new one is characterized by the fact that it should not be part of the technical level because objects included in the elements of the technical level, to establish the originality of the invention (utility model), should be considered only separately. The right to register such an object of intellectual property rights belongs to the inventor, unless otherwise prescribed by law. This right may also be granted to the inventor's employer (Law of Ukraine "On Protection of Rights…", 1993).

Therefore, it is possible to determine the following conditions for granting legal protection of an invention (utility model): compliance with public order; compliance with the principles of humanism and morality; compliance with patentability conditions. Therewith, as scientists emphasize (Mills, 2016; Ponomarova, 2021), ethics, morality, and law are interrelated components and are critical for society to accept the invention.

Special attention should be paid to the ethical component of patenting biotechnologies. The EU has taken measures (both organizational and institutional) to develop legal and ethical standards for biotechnology. In 1998, the European Parliament and the Council of the EU adopted Directive 98/44/EC on the legal protection of biotechnological inventions (1998). The need for such a Directive was conditioned upon the extraordinary growth of bioengineering research in the EU and, at the same time, the uncertainty of researchers regarding the possibility of patent protection of their scientific results, since the international documents adopted until now did not provide clear answers to some questions.

Article 5 of Directive 98/44/EU stipulates that "the human organism at various stages of its formation and development, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot be patentable inventions" (Directive 98/ 44/EC…, 1998). Furthermore, Article 6 of the Directive establishes that inventions are considered unpatentable if their commercial use would be contrary to public order or morality. This rule is generally accepted. The following are not patentable: processes of human cloning, processes of genetic modification of the human germline, use of human embryos for industrial or commercial purposes, processes of changing the genetic identity of animals that may cause them suffering without any essential medical benefit to humans or animals, and also the animals that result from such processes.

Based on the analysis of international legal acts, I.M. Shyshko (2021) established two criteria for compliance of biotechnological inventions with norms of public morality and public order, namely: primary (non-injury to human life and health) and secondary (respect for human dignity). In this case, A. McMahon (2017) draws special attention to the need for a correct and uniform interpretation of these categories (non-harm to human life and health, respect for human dignity), since the lack of a clear definition of terms and an elevated degree of their assessment substantially complicate the establishment of compliance of inventions with patentability conditions.

National legislation also contains outlined provisions. Pursuant to the norms of public morality, Article 6 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" (1993) lists the following objects as unpatentable: cloning processes of human beings; transformation of the germline to change the genetic identity of people; use of human embryos for industrial or commercial gain; changing the genetic identity of animals, etc.

In this regard, the World Intellectual Property Organization emphasizes that the life and health of people, as well as safety, should be more important than the patent rights of inventors (The ethics of patenting..., n.d.). Ethics and innovation in today's world must always go hand in hand.

Legal basis for restricting the rights of patenting entities in the field of biotechnologies

In the context of scientific and technological progress, humanity has recognized the importance of public control in the field of scientific achievements, the use of which may pose a danger to its life and existence in general. Therefore, apart from precautionary measures outlined in the Convention on Biological Diversity (1992) and the Cartagena Protocol on Biosafety (2000), there is an active discussion of the main international standards that can provide a comprehensive assessment of the risk arising from the use of biologically hazardous technologies (Association Agreement..., 2014). Investigating the issue of ensuring the human right to life in the conditions of the development of biotechnology, T.N. Kharatian (2018) pays considerable attention to the international practices regarding the organization of legal regulation of achievements in the field of bioscience. The scientist draws attention to the preventive norms, which make impossible the occurrence of catastrophic consequences of high-tech activities, in which biotechnological discoveries are used.

The use of biohazardous modern technologies and methods is accompanied by the creation of biological weapons of mass destruction in the form of dangerous genetically modified viruses and bacteria, and therefore, in the legislation of countries such as Colombia and Spain, the use of genetic engineering for the creation of biological weapons is a qualifying feature. Therefore, Ukraine needs immediate criminalization of potential socially dangerous activities in the use of biotechnologies. It is proposed to add qualified clauses to the Criminal Code of Ukraine (2001), namely: Article 439 "Use of weapons of mass destruction", Article 440 "Development, production, acquisition, storage, sale, transportation of weapons of mass destruction", Article 442 "Genocide" regarding the use and/or application of biotechnology to commit the specified criminal offences (Piddubny, 2014). In the fields of scientific research, healthcare, and product development, highly secure facilities play a critical role in preventing, detecting, and quickly and effectively responding to threats to global health security (Xia & Yuan, 2022).

Despite the inviolability of property rights, which is stipulated by the norm of Article 41 of the Constitution of Ukraine (1996), the legislation establishes cases that make provision for the forced alienation of such rights. These are cases when the object of property rights is important for public needs, but forced alienation provides for a legal basis and full compensation for the owner. In addition, forced alienation takes place in conditions of martial law and a state of emergency. If the issue concerns confiscation of property, then the only basis for such an act is a court decision, and confiscation is carried out only in the amount and according to the procedure prescribed by law. In general, the property is used on principles that do not violate the rights, freedoms, and dignity of citizens, the interests of society, do not adversely affect the environment and natural properties of the land (Constitution of Ukraine, 1996).

The Civil Code of Ukraine (2003), based on the Constitution of Ukraine, regulates an expanded list of intellectual property rights to the result of creative and intellectual activity, which means exclusive rights determined by the possession, use, and disposal of such rights, but they do not

have absolute nature and legally prescribed restrictions on them. That is, the restriction of public rights occurs in the presence of public, state and public interests.

The term "restriction of property rights of natural persons" is characterized by (Michurin, 2009), understanding it as a system of civil law instruments implemented in the process of legal regulation, embodied through legal norms, normative documents, acts of law application, the main purpose of which is the complication of subjective rights regarding the implementation of security measures for the interests of the state, society, and the public.

The Civil Code of Ukraine, namely part two of Article 424, regulates restrictions on intellectual property rights, provided that these restrictions will not prevent the use of intellectual property rights and the realization of the legitimate interests of relevant entities (Civil Code of Ukraine, 2003). Thus, the Law of Ukraine "On Protection of Rights to Industrial Designs" (1993), prescribes the possibility of consent granted by the Cabinet of Ministers of Ukraine regarding the use of an industrial design, the right to which is certified by a patent, without the consent of the owner, but under the condition that the use of such a patent arises from public interests or national security.

In the author's theses, R. Yurkiv addresses the fact that the above-mentioned procedure does not regulate the relationship of granting a compulsory patent for medicinal products. The scientist draws attention to the Law of Ukraine "On Medicinal Products" dated April 4, 1996, which contains a provision on the possibility of using a patented invention (utility model) in the field of medicinal products without the patent owner's consent. Considering the subject matter of the mentioned law, such permission is granted by the Cabinet of Ministers of Ukraine solely to ensure the health of citizens during the procedure for registering a medicinal product. Accordingly, the Resolution of the Cabinet of Ministers of Ukraine No. 877 "On approval of the Procedure for granting by the Cabinet of Ministers of Ukraine a permit for the use of a patented invention (utility model) relating to a medicinal product" dated December 4, 2013 was developed, which clearly regulated the procedure for issuing a permit for a compulsory patent for use of the medicinal product (Yurkiv, 2019).

International documents also define the possibility of compulsory patenting. Such acts are the Agreement on Commercial Aspects of Intellectual Property Rights (1994), the Paris Convention for the Protection of Industrial Property (1883). In them, it is considered appropriate to use a patent without the consent of the patent holder by the government of the country taking part in the agreement. Furthermore, it can also be applied to third parties, but only in an emergency or circumstances of extreme necessity.

The problems of the development of biotechnology and the use of its results have now become extremely relevant in connection with powerful technological advances, and the modern world patent system has a favourable effect on innovation and development (Feeney *et al*., 2018; Guerrini *et al*., 2017). However, if earlier scientific research in the field of biotechnology was based on the openness and access of the entire scientific community to their progress and results, now it has become a commercialized and monetized field. Moreover, there is currently a tendency to increase the adverse impact of biological factors on the population and the environment, the possibility of threats of biological origin associated with the development of modern biotechnologies, manifestations of bioterrorism, etc.

To ensure biological safety, the progress of modern biotechnological achievements should

set new ethical and social challenges for society. And the national policy in the field of biotechnology should primarily be based on the principle of maintaining a balance between ethics and intellectual property rights for biotechnological research. In this part, EU law as a whole is based on ethical principles. In the field of biotechnology, e.g., Directive 98/44/EC (1998) directly prescribes the possibility of regulating controversial issues of patenting biotechnological inventions by criteria of ethics and morality. Since ethics, morality, and law are interrelated components and are crucial for the adoption of the invention by society and ensuring biological safety at the same time.

Conclusions

Thus, according to the study results, the content of biotechnologies as an object of intellectual property rights is revealed. It is established that biotechnological scientific discoveries can considerably improve the health and life of people, improve the state of the environment, but the use of such technical processes also carries a potential danger. Despite the positive factors, the activity of the use of biotechnology has the ability, including destructive actions, and, as a result, can be a threat to the biological safety of humankind. Biotechnology is a tool of the future, which solves the problems of humanity already now, so there is an urgent need for high-quality legal regulation of such activity.

The analysis of international and national legislation helped characterize the legal bases of restrictions on the rights of patenting subjects in the field of biotechnology and identify areas in which it is prohibited to patent the results of biotechnological research, as well as existing limitations of the patent-protected powers of subjects of intellectual property law. The conditions for patenting inventions in the field of biotechnologies are regulated by legal norms, which consolidate the fundamental principle of compliance of inventions with ethical principles. And although biotechnologies demonstrate unprecedented progress and have a considerable impact on economic development, the legal regulation of biotechnological research should be focused on sustainability criteria, where social and environmental impacts should be prioritized. That is, the main aspect that needs to be considered to guarantee biological safety and the successful development of biotechnologies is the improvement of relevant national legislation in favour of economic development, environmental protection, and social well-being. In this regard, further scientific developments will be aimed at identifying trends in the development of legislation in the field of intellectual property based on the results of biotechnological research.

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Conflict of Interests

None.

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Олексій Юрійович Піддубний
Доктор юридичних наук, професор
Національний університет біоресурсів і природокористування України
03041, вул. Героїв Оборони, 15, м. Київ, Україна
https://orcid.org/0000-0003-4867-4613
Марина Андріївна Дейнега
Доктор юридичних наук, доцент
Національний університет біоресурсів і природокористування України
03041, вул. Героїв Оборони, 15, м. Київ, Україна
https://orcid.org/0000-0002-4785-7509

Анотація

Актуальність досліджуваної теми зумовлено стрімким та активним розвитком біотехнологічного напряму. Цей сегмент економіки та науки потребує не тільки комплексної попередньої роботи, а й подальшого правового захисту інтересів винахідників та суспільства. Розвиток біотехнологій регламентує не тільки сьогодення, а й перспективи майбутнього. Але важливо гармонізувати застосування біопроцесів, щоб уникнути біологічної катастрофи. Мета проведеної роботи – вивчити можливі правові інструменти обмеження захищених патентом повноважень суб'єктів права інтелектуальної власності задля гарантування біологічної безпеки. Для збирання, обробки та викладення інформації в роботі використано такі методи: загальнонаукові (формально-логічний, аналізу та синтезу, порівняння, індукції та дедукції, систематизування) і спеціально-юридичні методи (формально-юридичний, порівняльно-правовий). У статті розглянуто питання можливостей обмежити права, надані суб'єктам патентування, задля гарантування біологічної безпеки. Здійснено аналіз міжнародного й українського законодавства в аспекті патентування біотехнологічних досягнень, примусового патентування та обмежень прав суб'єктів патентування. Визначено юридичну природу біотехнологій як об'єктів права інтелектуальної власності. Висвітлено правові заходи обмеження захищених патентом повноважень суб'єктів права інтелектуальної власності. Звернуто увагу на правове закріплення вирішення суперечливих питань у сфері патентування біотехнологічних винаходів критеріями етики й моралі. Обґрунтовано необхідність удосконалити національне законодавство, що регламентує питання біотехнологічних досліджень з урахуванням принципу сталого розвитку, за яким пріоритетними мають визнаватися соціальні та екологічні аспекти. Значення наукової роботи посилено підвищеним попитом на біотехнології, що має наслідком певні правничі дії, пов'язані з їхньою охороною. Стаття стане в пригоді науковцям у сфері права, медицини, біоінженерії

Ключові слова: біотехнології; інтелектуальне право; біоресурси; патентне право; обмеження прав