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Fundamentals of Patent Protection in the Field of Biotechnology

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Abstract

This article covers the concept of patent protection bases in the field of biotechnology. The urgency of the work lies in the need to establish and determine the relationship between patent protection of biotechnology and the legislation of Ukraine, as there is no proper regulation in national legislation. The purpose of the study is conditioned upon the analysis of certain legal issues of biotechnology protection, the need to highlight the features of the legal regulation of relations in the field of biotechnology in international and Ukrainian regulations. During the study, the authors used the following methods to obtain, process and present information: general science (formal-logical, methods of analysis and synthesis, comparison, methods of induction and deduction) and special-legal methods (formal-legal, comparative-legal). The results of the study revealed some inconsistencies in the legislation of the European Union, in particular in the provisions of Directive 98/44 on the conformity of the concept of model, but at the same time worked out the scope of relevant regulations and their functions. It is investigated that there are certain ethical problems in the aspect of human cloning and further development of mankind. The need to adjust the current legislation has been identified. The results of this work, including its components, can be useful for both lawyers in the field of intellectual property law and medical professionals. The practical significance of the article is characterised by a comprehensive study of patents in the field of biotechnology, and an attempt to amend existing Ukrainian legislation in the field of patenting and intellectual property law. The authors consider it expedient to adopt the Law of Ukraine "On Biotechnology Protection", which should provide criteria for compliance with publicity and morality, based on Ukrainian law, when inventions as an object of intellectual property rights can be considered non-patentable

Keywords: health care, patent law, agriculture, intellectual property rights, intellectual law

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Introduction

What does it take for society to accept a person's copyright in an invention? Morality, law and patent. Patent law in the countries of the European Union is based on the legal principles of ethics and morality. The adoption of Directive 98/44 on the legal protection of biotechnological inventions [1] was carried out to develop the economic sphere of the European Union, the ability to manage conflicting ethical and moral criteria for patenting biotechnological inventions to regulate European Union law.

Biotech companies are structures that have the potential to change healthcare relationships forever. Complexes that create the latest drugs, vaccines and other substances that are aimed at improving the health of patients and receive significant profits from patented biotechnological inventions in medicine, pharmacy and more. For similar corporations, an equally important aspect is to take measures to protect the research and technology that accompanies the breakthrough in the medical field through the acquisition of patents for inventions. At the beginning of the COVID-19 pandemic, concerns about access to coronavirus drugs worried not only society but also political circles, but later the World Health Organisation, with the support of the European Commission, publicly acknowledged that intellectual property was not an obstacle to increasing vaccine production. drugs against COVID-19 [2, p. 25-26]. An article in the medical journal Expert Review of Vaccines fully justifies the need to abandon the patent for the COVID-19 vaccine in favor of increasing their global production [3].

Given the uniqueness and specificity of patenting a biotechnological object as an object of intellectual property rights, it is necessary to clarify the problematic issues arising from the specific features of the legal regulation of relations in the field of biotechnology.

This issue was raised, in particular in the works of such Ukrainian scientists as: L. Ponomareva and her article [2], which presents the results of a study on the patenting of biotechnological inventions in medicine and pharmacy, including an analysis of the positive aspects of biotechnology in this area, which enable people with disabilities to get a chance at life and solve certain problems related to health, with the help of modern advanced achievements of science; V.G. Gerasimenko, M.O. Gerasimenko, M.I. Tsvilikhovsky [4], who studied in detail biotechnology as a field of biology and studied the current state of biotechnology, fundamentals and practical use of biotechnological developments in such areas as veterinary medicine, animal husbandry, ecology and related sectors of the economy in his textbook.

However, a clear legal approach to patenting in the field of biotechnology has not yet been formed, and there are gaps in modern Ukrainian legislation in terms of patent law.

The purpose of this article is to analyse the legal issues of biotechnology protection, to highlight the features of the legal regulation of relations in the field of biotechnology in international and Ukrainian regulations.

Materials and Methods

The authors, collecting and analysing information for the work, used the following methods: general scientific, namely formal-logical, comparison, methods of induction and deduction, and special-legal, ie formal-legal, comparative-legal methods. Among the materials that the authors decided to use during the study — a significant part — the work of foreign scientists, which are indexed in international databases such as Scopus and Web of Science, such as articles such as "Morality: An important consideration at the patent office" [5] and "Patenting biotechnological inventions in Europe" [6]. With the help of general scientific methods, namely the method of comparison, the Ukrainian legislation in the field of patenting of biotechnologies was compared with the international one; using the method of induction and deduction, problem issues are identified and ways to solve them are suggested. Special legal methods, namely formal-legal and comparative-legal, contributed to the legislative elaboration of materials and legal support of the conclusions made. Another important component of the materials is international law, such as the European Union Directive [1].

Results and Discussion

Today's achievements in the field of biotechnology and artificial intelligence in the context of modern ideological concepts threaten the loss of the basic concept of humanity. The question of morality in the case of "patenting life" still remains open. The existing position of the European Patent Office on the morality of patenting biotechnological inventions follows from the cases before it. Inventions such as oncomys (the first patented transgenic organisms) cannot be excluded from patentability on the basis of immorality if their positive aspects outweigh the disadvantages [7].

It is necessary to pay attention at first to features of legal regulation of relations in the field of biotechnologies in the international legislation. The development of genetic engineering is inextricably linked with the use of human biomaterials, which causes even more ethical problems [8]. In particular, it should be noted that the Italian National Committee for Bioethics on June 22, 1996 approved the document "Identity and status of the human embryo" [9], according to which the human embryo is recognised as worthy of respect and care applied to human individuals, which are assigned personality characteristics. This document reads as follows: "The Committee unanimously agreed to recognise the moral obligation to treat a human embryo from the moment of fertilisation (conception) in accordance with the criteria of respect and care applicable to human

individuals who are assigned a personality" [10]. That is, the Italian National Ethics Committee recognises the embryo as a person. It should be noted that according to Part 5 of Art. 221 of the Association Agreement between Ukraine and the European Union and the Atomic Energy Community and their Member States on the other hand [11], inventions will be considered non-patentable in cases where their use in commercial activities is contrary to ordre public or public morality; nevertheless, the use of inventions is not considered as such only because of the prohibition in accordance with laws or other regulations. In summary, we can say that the following objects are considered non-patentable:

a. the processes of human cloning;

b. processes of modification of the germ line of human genetic identity;

c. the use of human embryos for industrial or commercial purposes;

d. processes of modification of the genetic identity of animals that are likely to cause their suffering without any significant medical care for humans or animals, including animals resulting from such processes [11].

The provisions of parts 9 and 10 of Art. 221 of the above-mentioned Agreement [10], according to which "legal protection does not apply to biological material obtained from cultivation or reproduction placed on the market of biological material in the territory of the Parties by the patent owner or with his consent, where reproduction or cultivation is mandatory the result of the application for which the biological material has been marketed, provided that the resulting material is not subsequently used for other cultivation or propagation. The sale or other form of commercialisation of plant cultivation material to a farmer by the patent holder or with his consent for agricultural use means the farmer's permission to use the product of his harvest for cultivation or propagation by him on his own farm. At the same time, the distribution and conditions of this partial repeal may be consistent with the conditions provided for in the national laws, regulations and practices of the Parties regarding plant variety rights" [12].

On the other hand, there is a majority to whom these technologies are provided in doses or not at all. The former may suffer from the erosion of human identity, the latter from large-scale discrimination that has no precedent in history. If earlier at all stages social strata were always more or less permeable for the lower levels, then the newly acquired biological properties or expanded knowledge of the existing ones will make these barriers insurmountable. For example, people who have not received from birth some artificially programmed abilities, resistance to disease, will be in a conscious repressed position and will not be able to fix it.

On the one hand, advantages will be given to their more successful competitors with the edited gene, and on the other hand, systems of knowledge about the properties encoded by genes will not leave less well-off individuals a chance to hide these shortcomings. Modern legal issues in the field of biology and medicine also include the following: the ability to conduct experiments with human embryos after reaching two weeks, the possibility of using for scientific and medical purposes chimeric embryos, including methods of genome editing involving human genes and animals together, methods and processes used to change the structure of human DNA.

New technologies allow interfering in the human genome, which can lead to certain consequences for the further development of mankind. Although there will always be a dependence on genetic materials, there is a tendency for research and development activities using genetic materials to be increasingly supplemented or replaced by computerised research activities. The growth of big data raises some legal issues in terms of data ownership and intellectual property, data management and administration, including technology transfer and licensing [13].

Innovation is stimulated by the emergence of a pathogen, such as the elements or disease, so the COVID-19 pandemic demonstrates this once again. Thus, according to statistics [14], the connection between intellectual property and innovations in the field of biotechnology and drug development has been confirmed. Most impressed by the high performance in 2021 in medical technology, pharmaceuticals and biotechnology. In contrast to the total number of applications for European patents in the technical fields, which decreased, these three areas violated the trend and showed an increase of 2.6% (in the field of medical technology), 10.2 % (in the field of pharmaceuticals) and 6.3% (in the field of biotechnology). The terrible pandemic that engulfed the world in 2020 affected all aspects of the economy. The tourism industry has been severely affected by restrictions on travel and entry, but digital technologies have played a very important role in transforming the usual online style of work [14].

Thus, biotechnology is one of the priorities of modern science, which accelerates scientific and technological progress, and is an effective way to overcome problems in the field of raw materials, energy, food, economics and ecology. It finds its purpose in solving many practical problems, which are closely interrelated with increasing the efficiency of innovations in the field of human and animal health, reducing harmful effects on the environment and the ecosphere, increasing the rational use of food resources and raw materials, and the use of affordable, waste-free and efficient energy sources [4, p. 9].

Article 2 of the Convention on Biological Diversity of 06/05/1992 [15], defines the term "biotechnology" as any type of technology that involves the exploitation of biological systems, living organisms or their derivatives for the purpose of manufacturing, modifying products, or processes for a specific application.

Despite the use of biotechnology in production

and various spheres of human life, the most pressing issues related to innovation in biotechnology are the protection of intellectual property. Today, the protection of intellectual property rights in the field of biotechnology is one that is not able to fully protect the subjective rights of Ukrainian owners and other legitimate users of intellectual products. Legislative regulation of these processes in the Ukrainian legal field is virtually absent.

From a commercial standpoint, the authors of this work pay attention to the technology of Crisper (CRISPR) [16], which is known as genetic engineering. Its emergence has led to a fivefold increase in investment in genome-editing bio-enterprises over the past year. This entrepreneurial movement has stimulated the global biotech revolution in the implementation of new gene editing technologies. Such global shifts in the bio-enterprise will only increase as the demand for personalized medicine, genetically modified plant crops and environmentally sustainable biofuels grows. However, the monopolisation of intellectual property, the public's negative perception of genetic engineering and ambiguous regulatory policies may limit the growth of these market segments, with which O. Piddubny and O. Svitlychny agree.

The content of technology, which is a mandatory attribute of biotechnology, biological processes, etc., may contain more than one object of intellectual property rights (invention, plant variety, animal breed, trade secret). To clarify the protection of biotechnology, we will analyse the regulatory and legal support of this process.

Given the above, consider the features of the legal regulation of relations in the field of biotechnology in national law. It should be noted that today in Ukraine there is no special legislation that would regulate legal relations in the field of legal protection of biotechnology. This issue is briefly regulated by the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" of 12/15/1993 No. 3687-XII, in Art. 1 of which biological material means "material that contains genetic information and can self-reproduce or be reproduced in the biological system", and part two of Art. 6 of the Law stipulates that "the object of the invention, which is granted legal protection, may be a product (device, substance, strain of microorganism, cell culture of plants and animals, etc.) or process (method)" [17].

In contrast to the Law of Ukraine "On protection of rights to inventions and utility models" [18], the Rules of preparation and submission of applications for inventions and applications for utility models from 01/22/2001 No. 22, regulate this issue in more detail, referring to objects of technology material objects as the results of human activity, in particular: "device, mechanism, system (complex) of interacting devices, structure, product, substance, strain of microorganism, cell culture of plants and animals and other biological material, including transgenic plant and animal" [18].

Given the problematic issues of protection of biotechnological inventions, the European Parliament and the Council of the EU in 1998 adopted Directive 98/44 on the legal protection of biotechnological inventions, which provided some answers to questions that arose in practice [19].

In particular, Art. 5 of Directive 98/44 [1] stipulates that: first, "the human body at various stages of its development, including the simple discovery of one of its elements, and the sequence or partial sequence of a gene", may not constitute patentable inventions; secondly, an element isolated from the human body or otherwise obtained by a technical process, including a sequence or partial sequence of a gene, may constitute a patented invention, even if the structure of this element is identical to the structure of a natural element. Art. 6 of the Directive [1] stipulates that inventions will be considered unfit for patenting if their commercial operation is contrary to public policy (ordre public) or morality. This norm is generally accepted.

In particular, the following cannot be patented: "processes of human cloning, processes of genetic modification of human germ lines, use of human embryos for industrial or commercial purposes, processes of changing the genetic identity of animals that can cause them suffering without provoking significant medical benefits for humans or animals, including animals that are the result of such processes" [20].

In addition, Directive [1] does not provide an answer to the three objections that inevitably arise in the analysis of this distinction. First, the study of almost any natural object is possible only after its previous removal from the natural environment, otherwise any action on it does not seem possible. Second, even if the natural element is isolated from the natural environment, it does not change its "natural" nature. The indication of the technical nature is an argument only in favour of the patentability of the isolation process, but not in favour of the patentability of the isolated product [21, p. 124].

Third, the Directive [1] does not contain definitions and criteria of "manufacturability", which must meet the processes by which the isolation and/or production of biotechnological products. This allows interpreting "manufacturability" unnecessarily widely and extend it even to standard and well-known processes and mechanisms used in biotechnology [22]. Of particular importance is this objection in challenging the patentability of gene sequences, the patenting of which was originally in demand conditioned upon the technical complexity of the process of their isolation. Currently, this process is carried out by specially created computers and is a standard procedure that requires only minimal human involvement [23, p. 492].

In this regard, the Directive [1] leaves unresolved the question of whether this technical process must meet the criteria for obtaining a patent, and if not, on what basis the product obtained as a result of such a process can acquire the status of a patentable invention.

Thus, the establishment of legal properties and guidelines for the interpretation of the concepts of morality and public order at the European level, enshrined in Art. 6 of the Directive [1], partly contradicts the provision of the Directive itself on the need to interpret these concepts in accordance with the national law of each EU member state. This contradiction should be resolved in favour of the preamble to the Directive for a number of reasons. First, the criteria for conformity of inventions to morality and public order cannot and should not be developed at the supranational (in this case, pan-European) level explained by the lack of a common notion of moral values and the impossibility of extending artificial norms and standards to different legal systems. Secondly, the aim of harmonising EU law is to create a single market by establishing the principles of free movement of people, goods, services and capital. Unification of concepts in the field of morality, culture or religion, the definition of which does not have clearly defined boundaries, belongs to the internal competence of the state [24, p. 12]. This position was also confirmed by the Court of Justice in a number of court cases [25, p. 7161].

Indeed, the notion of moral values varies by country. Even in developed European countries, such as the Netherlands and Poland, Germany and the United States, there are different moral ideas and principles in human life that express moral orientation and influence individual behavior through the prism of personal perception. The above can not but affect the creation of an intelligent product. For example, US law does not provide grounds for refusing a patent for moral reasons, other than patenting human-animal hybrids and keeping human stem cells in an animal [25]. But recent developments in biotechnology have opened up new opportunities not only for research but also for patenting. However, recent decisions of the US Supreme Court, such as in the case of the Association of Molecular Pathology v. Myriad Genetics [5], demonstrate the difficulty of interpreting these new technologies in patent law. Many scholars, for example, have argued that instead of using the "product of nature" doctrine [5] and focusing on the boundary between human and natural constructions, the Court should have ruled on the doctrine's political goal: to protect basic research tools and technological works. Failure to comply with this requirement has led to confusion in doctrines, reduced patent protection and increased uncertainty in the field. In addition, recent biotechnological developments also raise increased ethical concerns

The German patent law provides for special provisions that apply primarily to humans. The human body cannot be patented during certain stages of formation and ontogenesis, including germ cells (Section 1a of the German Patent Law) [26].

Legal protection of biotechnology is regulated by the Agreement on Trade-Related Aspects of Intellectual Property Rights of the WTO, according to Art. 27 Agreements [27] patents are granted for any inventions, products or processes in all fields of technology, provided that they are new, include an inventive step and are suitable for industrial use. However, the members of this Agreement "may refrain from patenting inventions the commercial use of which in their territory is prevented by the protection of public order or public *morals*, in particular the protection of life or health of humans, animals or plants, or which is necessary to prevent significant damage to the environment, provided that such an exception is not made simply because their use is prohibited by law, and do not allow patenting:

a. diagnostic, therapeutic and surgical treatments for humans or animals;

b. plants and animals, other than micro-organisms, and important biological processes for the production of plants or animals, other than non-biological and microbiological processes. However, members must ensure the protection of plant varieties either through patents, or sui generis an effective system, or through their combination" [27].

Therefore, inventions in the field of biotechnology are non-patentable in cases where their commercial use is contrary to public policy.

At the international level, the legal protection of biotechnology is also regulated by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 04/28/1977 [28] and the European Patent Convention of 10/07/1977 [29], which examines applications for formal requirements, including examination of patent applications for compliance with the requirements of patentability — novelty, inventive step, industrial applicability.

It is worth noting that advances in biotechnology have led to the development of numerous fundamental bioprocesses that have combined research and development, and industrial progress in this field. These bioprocesses are used in medical therapy, diagnostic and immunisation procedures, agriculture, food production, biofuel production and environmental solutions (to solve problems related to water, soil and air), and among other areas. Therefore, the authors of this article believe that there is an urgent need to ensure the greatest possible protection of such processes at the international and national levels [30].

Given the focus of the research, it should be noted that in some cases it is particularly difficult to identify the invention as new and previously unknown, because sometimes such cases relate to substances in their natural state. Such substances can be considered new, in the opinion of the European Patent Office, if they were isolated for the first time and the existence of which was not previously known. The same applies to microorganisms. The DNA sequence, although located in a known gene library, is not considered new as long

as the special hybridisation zones required for its isolation and characterization are known (T 301/87 and T 412/93) [31].

Conclusions

Considering the above considerations, it can be concluded that modern science in the field of biology and medicine, along with its significant achievements, raises many previously unthinkable ethical issues that need to be addressed immediately. If throughout human history the notions of ethics and morality have been revised along with the change of historical epochs, today we have a situation when every five to ten years society is asked another question that was difficult to imagine before. It is even more difficult to predict ways to address these issues, but it is absolutely certain that the biological, moral and philosophical concept of man will be significantly revised. At the same time, new aggressive and destructive methods of exploiting inequality on a new biological basis are not excluded. To regulate relations in the field of biotechnology, the Ukrainian legislator must consider the existing problems of legal regulation of patenting inventions, which are enshrined in certain articles of the Association Agreement between Ukraine on the one hand and the European Union, the European Atomic Energy Community and their Member States on the other.

Secondly, it is expedient to adopt the Law of Ukraine "On Protection of Biotechnologies", which provides for criteria of publicity and morality, based on Ukrainian legislation, when inventions as an object of intellectual property rights may be considered insolvent. In turn, the criteria of conformity of publicity and morality include the choice of the method of protection of violated rights or their combination. It is appropriate to predict the legal consequences of such a choice, which must be reflected in the provisions of this law.

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Основи патентного захисту у сфері біотехнологій

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Анотація

Дана стаття розкриває поняття базисів патентного захисту у сфері біотехнологій. Актуальність роботи полягає у необхідності встановлення та визначення взаємозв'язку між патентною охороною біотехнологій та законодавством України, оскільки відсутнє належне регулювання у національному законодавстві. Мета дослідження зумовлюється проведенням аналізу певних правових питань охорони біотехнологій, необхідністю виокремлення особливостей правового регулювання відносин у сфері біотехнологій в міжнародних та українських нормативних актах. Під час проведення дослідження автори використовували наступні методи для отримання, обробки та викладення інформації: загальнонаукові (формально-логічний, методи аналізу та синтезу, порівняння, методи індукції та дедукції) і спеціально-юридичні методи (формально-юридичний, порівняльно-правовий). За результатами дослідження виявлено деякі протиріччя у законодавстві Європейського Союзу, зокрема у положеннях Директиви 98/44 стосовно відповідності поняття моделі, але разом з тим опрацьовано сферу дії відповідних нормативно-правових актів та їх функції. Досліджено, що наявні певні етичні проблеми в аспекті клонування людей та подальшого розвитку людства. Виявлено необхідність коригування чинного законодавства. Результати даної роботи, а також її складові, можуть бути корисними як юристам у сфері інтелектуального права, так і медичним працівникам. Практичне значення статті характеризується всебічним дослідженням патентів у сфері біотехнологій, а також спробою внести зміни до існуючого українського законодавства у сфері патентування та інтелектуального права. Автори вважають за доцільне прийняття Закону України «Про охорону біотехнологій», в якому необхідно передбачити критерії відповідності публічності та моралі, виходячи із українського законодавства, коли винаходи як об'єкт права інтелектуальної власності можуть вважатися непатентоспроможними

Ключові слова: охорона здоров'я, патентне право, сільське господарство, права інтелектуальної власності, інтелектуальне право