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# Principles of Patent Protection in the Field of Biotechnology in Eastern Europe: Influence of Western and Eastern Models

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***Abstract***

The relevance of this research is explained by the necessity of a comprehensive study of the subject of patent protection in the field of biotechnology in Eastern European countries, which is conditioned upon the rapid development of technologies in the field of biology, medicine and pharmacy. The purpose of the research is to provide a legal assessment of the principles of patent protection and to develop approaches to the qualification of biotechnological achievements. While compiling the research, the author used general scientific methods: analysis and synthesis, induction and deduction, abstraction, specification and analogy. Among specific scientific methods, the statistical method is distinguished; notably, specific legal methods, such as comparative legal and method of interpretation of legal provisions. The results of the study highlight the main achievements in the field of biotechnology and promising ways of developing their patent protection. The research describes in detail the fundamental principles of patent protection of biotechnologies. The necessity to consider the possibility of alienation of patents in favour of the state for some inventions, if these inventions are essential at the level of the state and society, to ensure equal and free access to such technologies. It is stated that it is unacceptable to grant patent protection, especially to the results of research in the field of human cloning or the development of artificial intelligence on human cells, as it contradicts ethical and moral standards. The final part of the research is the conclusions of the study, which identify the significance and provides an assessment of the impact of biotechnology on the present and future. The results of the research may be useful for lawyers and scientists in the field of intellectual property law

***Keywords:*** biology, intellectual law, medical law, protection of intellectual rights, intellectual property

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## *Introduction*

Relevant to the research in the context of the protection of human rights and databases containing genetic information is the legislation of leading Western countries, as the rest of the world is only able to perceive the technology, and the archaic philosophical, ideological, and legal foundation for the protection of the rights of patent owners, contrary to the rights and demands of the rest of society. Thus, countries have, for the most part, neglected the development of intellectual property law, recognising that patent owners from other countries will interact in their territory, and expecting international provisions in this area – as demonstrated by a comparison of the types, cultural values and legal protection offered in place of conventional and/or indigenous knowledge in three zones: Brazil, Kenya and Canada [1].

Thus, in Western countries, patent legislation is the foundation of powerful research industries, which involve scientific potential and significant financial resources. Regrettably, such benefits do not benefit the entire society but only large corporations.

In conditions when no ideology can be defined by the state as mandatory (Article 15 of the Constitution of Ukraine [2]), and the church and religious institutions are separated from the state (Article 35 of the Constitution of Ukraine), bioethical principles can be a valuable indicator for the progress of society. It is expected that without the achievements of bioethics and biophilosophy it is difficult to develop bio-law, meanwhile, the volume of bio-law is growing rapidly, sometimes contradictory and unsystematically. Notably, the regulatory definition of "biosafety" as defined in the Law of Ukraine "On the State Biosafety System in Creating, Testing, Transporting, and Using Genetically Modified Organisms" [3], demonstrates a discrepancy between the term and its content (as proper understanding signifies the understanding of biological safety as the safety of biology – the science of living); Article 16 of the Constitution of Ukraine declares the obligation, to preserve the gene pool of the Ukrainian people, while the Concept of Health Protection of Ukraine [4] provides "strengthening the gene pool" etc., from which we conclude that the establishment of bio-law and bio-law requires collaborative work of philosophers, ethicists, ecologists, healthcare professionals, lawyers [5].

Consider that this approach should be supported, since only legal awareness of the phenomena of objective reality as lawful or unlawful, or attribution of such phenomena to different spheres of legal regulation with a varying correlation of public and private components will allow the developing of a model that provides for sustainable development of humanity. In particular, one such phenomenon that requires proper classification is the legal qualification of biotechnological achievements [6, p. 52].

While collecting information, the author used both national literary resources and the foreign latest research. The materials were based both on textbooks of Ukrainian authors and scientific research in foreign journals, for example, the research "Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome" in the journal "Science" [7], in which scientists designed a cell that will be controlled by a synthetic chromosome. In addition, the author referred to a recent study by Bridget Tenni et al, namely their research, "What is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review" [8], in which authors measured the impact of intellectual property regulations on access to medicines. Analysis of the legislation of the European Union and its impact was supported by the research of K. Shahbazyan "Protection of Inventions in the Field of Biotechnology in the EU and Ukraine" [9], which assessed the controversial European provisions on the patentability of biotechnological products and considered the issues of ethics, morality and criteria in patent protection. As India has occupied a leading position among other countries in filing patents in recent years, it is hard to argue that this has not had an impact on patenting in Eurasia, so the author considered the research by Jobin Jose et al "The Benefits and Barriers of Patenting: How Academicians and Researchers Can use their IP to Improve Research Outcomes: An Indian Perspective", which explores the problems and benefits of patenting inventions in the field of medicine [10]. And the position of Ukraine and the establishment of the specific features of harmonisation of national legislation with the EU legislation in the aspect of pharmaceutical patenting was determined by the research of L. Deshko and O. Ivasyn "Patenting of Medicines in Ukraine through the Prism of the Association Agreement with the EU and the TRIPS Agreement: Improvement in Medical and Administrative Regulations" [11].

The purpose of the author's research is an in-depth analysis of the legislation of Eastern European countries, which are not members of the European Union, and determination of the extent of influence of the West and East models on the establishment of the principles of patent protection in the field of biotechnology. Before starting, the author of the research set the following objectives: to comprehensively examine the current legislation of the countries in Eastern Europe in the field of intellectual law and to provide a legal assessment of the vector of development of this field of law.

## *Modern national legal regulation*

However, it can be stated that the legal regulation of biotechnology and its intellectual property rights aspect in Ukraine is rather declarative and vague. Thus, by the Strategy of Economic and Social Policy for the period from 2000 to 2004, the development of the biotechnology industry was noted as one of the priority areas of national policy development.

In addition to the above, the protection of biotechnologies in the national legislation is performed by the Laws of Ukraine "On Legal Protection of Rights to Inventions and Utility Models" [12] of December 15, 2003, "On

the Protection of Rights to Plant Varieties" [13] of April 21, 1993, "On Breeding in Livestock" [14] of December 15, 1993, etc.

Thus, there are some foundations of legislative regulation, that can be analysed when trying to determine the legal qualification of biotechnology products and their legal regime, in particular as objects of environmental law or objects of intellectual property rights.

There is a huge divergence of opinion as to the patentability of living organisms, which are largely excluded from patentability. However, the way of thinking is changing rapidly, and much attention is being devoted to intellectual property issues in biotechnology. To reach global markets based on biotechnology, developing countries are amending their patent laws to encourage investment in biotechnology. Recent advances in biotechnological innovations have resulted in remarkable transformations in the field of genetics and molecular biology and have provided new perspectives in healthcare, pharmaceuticals and agriculture [15].

Biotechnology and bioprocesses are two essential tools for economic progress and social welfare. The industrial, academic and government sectors will inevitably encounter technical challenges as they develop competitive biotechnology products and processes using synthetic biology, genetics and molecular biology as alternatives to chemical applications. Therefore, the biological control of microbial consortia based on synthetic biology solutions, and the regulation and optimisation of the transition from batch production to continuous production are ongoing challenges [16].

The closest concept to biotechnology in the field of developing plant and animal breeds by conventional methods is breeding. *Breeding* – is an activity in the field of intellectual property concerned with the development (invention) of completely new, not previously bred seed resources as source material, further used in seed production for the propagation of highly productive varieties of grain crops [17, p. 138].

The modern science of agrarian law of Ukraine considers legal relations that have emerged through the development, protection, use, and alienation of new varieties of plants and new breeds of animals as relations in the field of breeding achievements. In addition, the authors note that the US patent law allows obtaining a patent, the invention of which is a plant. Currently, activities in the field of biotechnology, genetic and cellular engineering, and the establishment of new varieties and hybrids of plants by biotechnological methods are actively developing.

***Trendes in the development of patent law protection***

The author recommends that the prospective legal institute of patent protection of biotechnologies should be considered as a complex one, which should combine elements of environmental and other fields of law. In the context of this study, the main interest is not the civil law features of the protection of the rights of the inventor etc., but the ability of specific achievements to state registration and recognition in terms of nature management, or rather, using life as a universal biological resource, which causes a detailed environmental and legal regulation of the phenomena under study.

In other words, the ownership of life is a serious ontological problem for society. As pompous as it sounds, when it involves plant varieties, animal breeds, and breeding – activities that have surrounded humans throughout history – intellectual property, as a reward for years of effort, seemed legitimate. Currently, significant capital is actively invested in the development and patenting of nucleotide sequences that have not yet existed in nature and have not yet been fully explored, but they appear, and thus it can be stated that everything that surrounds them is patented. A similar process of "pirate registrations" by individuals who are not involved in the development of substances occurs in pharmaceuticals [18, p. 75].

A similar process, cybersquatting, i.e. registration of unoccupied Internet addresses that have a specific dictionary meaning, has long covered the "verbal space", Internet addresses that contain even the smallest and most absurd semantic load have long been reserved; the names of drugs are patented long before their development and determination of their medical effect, indications and contraindications. And now this process has affected the living world. It is as if someone patented the air they breathe cubic meter by cubic meter.

It is an essential issue concerning the privatisation of public legal space. Under the hegemony of capital, the fact that they still do not charge for the air they breathe or at least do not pay taxes for its use looks like a miracle.

However, it is not excluded that soon they will be forced to pay for their genes, as no biological resource, starting from the molecular level and above, can be in public use for a long time. All genes and biochemicals from various genomes that are of interest and promise income are in the process of patenting and privatisation.

Evidence of this tendency can be the fact of patenting azadirachtin derived from a tree called "neem", which grows in India. This tree has been used since ancient times to treat many diseases (primarily in the fight against infections) and is a natural pesticide. The scientist W.R. Grace identified the most significant component responsible for this effect (azadirachtin) and patented it. Although the process of extracting azadirachtin was known to Indian companies, they did not patent it: the neem tree, with its useful properties and known sphere of application, is considered to be in the public domain in India. In addition, using the neem tree for medical and other purposes has been known for many centuries. In a straightforward act of colonial aggression, which can be defined as eco-piracy, W.R. Grace has captured and maintains relative control over a public resource (it is encouraging to note that some countries refuse to acknowledge this patent) [19].

In this regard, information from the journal "Science" [7] is interesting, according to which a team of scientists first collected DNA sequences from chemical reagents. Based on the existing bacterium of the genus Mycoplasma, the sequence of genes was collected artificially with the addition of marker genes indicating the artificial origin of the collected bacteria. Such an organism is named *Mycoplasma mycoides* JCVI-syn 1.0. Craig Venter, a world-renowned specialist who managed the project, declared in this regard about the industrial revolution [7, p. 1], which would follow this discovery or invention. In the existing terms of law, it is currently difficult to establish what exactly was done by biologists – the discovery of new laws of nature or biotechnological invention. After all, it depends on the level of legal understanding and further legal regulation of legal relations that will necessarily be generated by this fact.

According to Yu.I. Kundiev provides a way to manipulate life on a scale that was previously considered unattainable. It is possible to design living systems with predetermined capabilities, in other words, programming living organisms, developing living organisms from the so-called "bio-bricks", and assembling DNA sequence fragment by fragment. Thus, this is a clear example of when "dangerous knowledge" increases it is potentially much faster than the wisdom that is required to cope with it [20, p. 28].

The requirement of the clearest and most complete description of the invention in the field of biology is one of the main obstacles in ensuring patent protection of the results of technological research [21, p. 362-365].

Conventionally, the essential features of breeding achievements include the presence of a biological object, the presence of genetically determined traits and obtaining as a result of purposeful selection [21, p. 410]. To this is added the predominant use in agricultural production, priority based on the world level of distinctiveness by biological features, is created exclusively in material form and requires organoleptic expertise [22, p. 7].

As noted by researchers of foreign sources, the instructions to the European Patent Commission currently outlining a biotechnological invention, biological material, plant variety and process in the field of microbiology, enshrine the principle of non-limitation to one particular plant variety or animal breed (i.e. if the technical embodiment of the invention is not limited to a particular plant variety or animal breed), and specified inventions deprived of patentability – "processes of cloning of human beings, processes of alteration through the germline of genetic identity of human beings, use of human embryos for industrial or commercial purposes; processes of alteration of genetic identity of animals which may cause them suffering without any significant medical benefit to humans or animals, and animals emerging as a result of such processes". [23, p. 23].

Interesting is the research of K. Shahbazyan, who notes: "Comparison of the provisions of the national legislation of Ukraine and Directive 98/44/EC testifies to the expediency of implementing into our legislation all the fundamental principles specified in the Directive concerning the patentability of biotechnological inventions, the scope of their protection, licensing conditions, conditions of deposit and access to them, etc." [9].

The justification for this position is that even historically in the European Union, several reasons determined the necessity to harmonise the legislation of the Member States on the protection of biotechnological inventions. For example, one such reason is the diversity that exists in the systems of legal protection for inventions in the European Union, which is expected to become an obstacle to commerce and market development in the future; and the progression of these differences in the adoption of updated national legislation and its interpretation by national courts in the European Union; and, admittedly, the realisation that only legal protection adapted to the requirements of the present will encourage increased investment in the biotechnology industry.

### *Solution of biopatenting problems*

However, the author notes the significant role of consolidation in the legislation of specific principles to be applied to the patentability of biological materials, which, in addition, promotes and intensifies the desire for harmony in the legislation. Notably, to comprehensively improve the multilevel system of legal regulation of research and development in the field of biotechnology, the Directive was approved in 1998 [24]. The harmonisation of biotechnology legislation in the European Union has now begun based on the European Parliament and Council Directive 98/44/EC on the legal protection of biotechnology inventions, which is designed to address issues in ethical terms and to encourage research and development.

The Directive states that "the following are the principles for patenting inventions in the field of biotechnology. Technological inventions suitable for industrial use are patentable even if they concern a product containing biological material or a process by which biological material is produced or used. Inventions concerning plants or animals are patentable if the technical embodiment of the invention is not limited to a particular plant variety or animal breed. The human body and its elements may not constitute a patentable invention, but an element separated from the body or produced in another way may constitute a patentable invention" [25].

In addition, biological inventions, which appeared contrary to the generally accepted provisions of ethics and morality in society, are not patentable, in particular: human cloning, using human embryos for industrial purposes and changing the genetic identity of a person.

According to the document, patent protection cannot be granted to inventions if they only compile previously acquired knowledge and are not used for new purposes. That is, there is no possibility to patent a DNA sequence since it is not an invention but only a discovery.

Instead, processes and products that use DNA sequences can become patentable if they comply with ancillary patentability criteria.

As a result, the author proposes to consider as unpatentable some processes, such as cloning of a human being, and changing its genetic identity; to determine that the human body at any stage of ontogenesis should not be an object that can be patented [26, p. 1].

In the author's opinion, without naming specific methods or techniques, it is necessary to consider the possibility of compulsory alienation of patents in favour of the state for those inventions that will be considered to be in the public domain and distributed freely or on predetermined, equal conditions for all with the possibility of access to each interested person.

## *Conclusions*

Considering the above, it is essential to reconsider the essence of the state as a social regulator of radically new social relations arising in connection with the development of biotechnology. Previously, due to a lack of appropriate instruments for penetration and manipulation, human biological beings seemed solely a private sphere, but now the state must regulate in detail all phenomena in the sphere of biological beings, above all human beings, considering those dangers and rights violations, increasing social inequality by biological inequality, which will be reflected in closing the access for most of society to using the achievements of biotechnology by various kinds of patent barriers. Thus, when deciding whether or not to grant patent protection to specific phenomena in biotechnology, the regulator should not be guided by the interests of the researcher, inventor or investor - although it would seem that prioritising such interests would contribute to the more efficient development of biotechnology, as advocated by the author of the research, but on the interests of the general public, on how such legal protection will affect the development of social relations and whether it will violate the fundamental ecological right of the individual to life and the free enjoyment of the environment in which they live. In this case, the author should proceed from the concept of administrative procedures in the field of intellectual property, not only as activities to protect and enforce the rights of intellectual property subjects but as activities to protect the public interest and free development of further research in the field of biotechnology.

The doctrinal determination of the development of biotechnology and its impact on nature and society should be based on the principle that the biological resource is single and indivisible, like atmospheric air, and cannot be an object of individual use. Similarly, the only biological resource – life is even more universal and the results of its use, all derivative life species established from existing ones, and those constructed from chemical compounds by assembling DNA helix segments, evidently cannot be artificially distinguished and become objects of civil rights.

And it is unacceptable to grant patent protection, especially to the results of research in the field of human cloning or the development of artificial intelligence on human cells, which can only encourage those who want to make a profit. The primary principle of legal qualification should be compliance with environmental rights and the legitimate interests of members of society, and only if this preliminary criterion is satisfied, should further ways of disseminating the phenomenon through intellectual property mechanisms, or recognition as a discovery and in the public domain.

To outline the prospects of national development, consideration should be devoted to the rapid development of industries related to medicine and pharmacy. According to the author, these processes are connected proportionally, thus, the significance and necessity of biopatenting will only increase.

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## Принципи патентного захисту у сфері біотехнологій у країнах Східної Європи: вплив західної та східної моделей

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***Анотація***

Актуальність цієї роботи зумовлюється необхідністю всебічного дослідження теми патентного захисту у сфері біотехнологій у східноєвропейських країнах, яка зумовлена стрімким розвитком технологій у галузі біології, медицини та фармації. Мета роботи полягає в наданні юридичної оцінки принципам патентного захисту, а також опрацюванні підходів до кваліфікації біотехнологічних досягнень. Готуючи статтю, автор використовував загальнонаукові методи: аналізу та синтезу, індукції та дедукції, абстрагування, конкретизації та аналогії. Серед спеціальних наукових методів виокремлюється статистичний метод;

також варто наголосити на спеціальних юридичних методах, як-от порівняльно-правовий та метод тлумачення правових норм. Результати дослідження висвітлюють основні досягнення у сфері біотехнологій та перспективні шляхи розвитку їх патентного захисту. У статті детально розглянуто базові принципи патентного захисту біотехнологій. Виявлено необхідність у розгляді можливості відчуження патентів на користь держави на деякі винаходи, якщо ці винаходи мають важливе значення на рівні держави та суспільства, для забезпечення рівного та вільного доступу для таких технологій. Зазначено, що є неприйнятним надання патентного захисту, особливо результатам досліджень у галузі клонування людини чи розробки на людських клітинах штучного інтелекту, оскільки це прямо суперечить етичним та моральним нормам. Заключною частиною роботи слугують висновки з проведеного дослідження, у яких розкривається значення та надання оцінки впливу біотехнологій на сьогодення та майбутнє. Результати роботи можуть стати в пригоді правникам та науковцям у сфері інтелектуального права

***Ключові слова:*** біологія, інтелектуальне право, медичне право, захист інтелектуальних прав, інтелектуальна власність