

THE PECULIARITIES OF LEGAL PROTECTION OF INVENTIONS IN THE AREA OF BIOTECHNOLOGIES: THE EUROPEAN EXPERIENCE

Vasyl Nastyuk, Yaroslav Mudryi National Law University
Anzhelika Krakovska, Vasyl Stus Donetsk National University
Maryna Utkina, Sumy State University
Iryna Slovka, National University of Water and Environmental Engineering
Roman Shapoval, Yaroslav Mudryi National Law University

ABSTRACT

The authors researched the peculiarities of the legal protection of inventions in the field of biotechnologies based on the legislation of European countries and Ukraine. They determined the legal framework regarding the legal protection of biotechnologies at the international level. They identified the fundamentals related to the peculiarities of judicial control and protection of biotechnological inventions in the European countries (Germany, the United Kingdom, France, and Italy) and the resolution of these issues at the legislative level in Ukraine. Particular attention was put to the provisions of Directive 98/44/EC of the European Parliament and the Council on the legal protection of biotechnological inventions. One determined the content of the rules of the current patent legislation in Ukraine, which regulates the protection of biotechnological inventions, and highlighted the key aspects of the Agreement between Ukraine and the European Union in the context of the conducted research.

The authors provided a systematic overview of the main requirements applied to the biotechnological innovations to determine their patentability. The main problematic aspects of the Directive 98/44/EC were highlighted based on the research findings. They lead to an ambiguous interpretation of the document's rules and the existence of considerable differences in the patent legislation available in the member countries of the European Union.

Keywords: Biotechnology, Invention in the Area of Biotechnologies, Patent, Patent Legislation, Patentability of Invention in a Field of Biotechnologies.

INTRODUCTION

The introduction of biotechnologies into production and their active use in economic activity occupy an essential place among the perspective directions of economic development of any state. This is due primarily to the fact that the practical capabilities of biotechnologies lead to the immense growth of inventions, which have a relation to the various biological objects. In particular, it is about the innovative ways of treatment of multiple diseases, protection of the environment, etc. The legal protection of inventions in the area of biotechnologies is carried out through various methods, among which are the grant of patents, know-how, the registration of the trademark, and protection via copyright regulations. The patenting of an invention is one of

the most popular methods of commercialization of biotechnologies. It is also one of the ways to compete with other companies for the sales market. That is why it is quite vital to protect biotechnological products at the level of legislation.

Problem Statement

The current stage of innovations development in Ukraine and the implementation of requirements set out in Ukraine-European Union Association Agreement require the enforcement of the state patent legislation to the European standards in this field. One considers it quite relevant to study the features of the legal protection of inventions in the area of biotechnologies with respect to both Ukrainian national legislation and International laws as well as the critical aspects of the legal protection of inventions in the field of biotechnologies following the law of the leading European countries.

LITERATURE REVIEW

The investigation of peculiarities of legal protection for inventions in the field of biotechnologies requires a study of experience received by the European countries during the search for the solution of the matter.

For instance, in Germany, people regard the German Patent Law (Patentgesetz, 1980) of 16 December 1980, and the Patent Costs Act (Patentkostengesetz, 2001) of 13 December 2001, as the primary regulatory legal acts in the resolution of issues related to legal protection. The Patent Law includes the list of objects which are under the protection of patents. It also highlights the order of patent acquisition, the structure, and the functions of the Patent Department and the Patent Court (Patentgesetz, 1980). The Patent Costs Act defines the amount, the date of payment, and the consequences of non-payment of patent expenses, etc. (Patentkostengesetz, 2001). It is noteworthy that the current German Patent Law does not consider the human body to be the patent invention on various stages of its establishment and development, including the germ cells, and the detection of its constituents, including the sequence or a partial sequence of the gene. At the same time, an isolated component of a human body or the one received via another way using a technical method, for example, the complete or partial sequence of a gene, might become a patent innovation even if its structure is identical to the composition of the natural constituent. The commercial applicability of the sequence or a partial sequence of a gene should be specifically described in the application specifying the function performed by the sequence or partial sequence (Patentgesetz, 1980). Thus, it is possible to conclude that the current Patent Law in Germany ensures innovations protection in the field of biotechnologies only in the part of the function, indicated in the patent application.

The United Kingdom has got the Patent Law Act, either. It dates back from 29 July 1977. The document regards each component obtained of the human body or through a technical process, which includes the sequence or a partial sequence of a gene, even if the structure of the component is identical to the natural one; as the patent innovation in the area of biotechnologies. At the same time, the law strictly determines that the patent application should clarify the industrial use of the complete or a partial sequence of a gene (The Patents Act, 1977). In this way, the British law provides absolute legal protection of inventions in the field of biotechnologies, including the sequence of a gene or its part. The British Intellectual Property

Office (IPO) is one of the central institutions providing legal protection to innovations. The Department for Business, Innovation & Skills (BIS) supervises it. Moreover, there are 13 Patent Libraries (PATLIBs) in the United Kingdom, whose primary function is the promotion of the issue resolution related to the intellectual property (Luzan, 2016).

The key provisions of the patent legislation in France are determined by the Intellectual Property Code (Intellectual Property Code, 1992) of 01 July 1992. The provisions of current patent law in France indicate that biotechnology-based products and traditional inventions cannot be regarded as identical in any way. Thus, the patenting of the gene sequence or its part in this country is prohibited, while the grant of a patent applies only to its industrial application (Intellectual Property Code, 1992).

The legal protection of inventions in the area of biotechnologies in Italy is carried out according to the rules defined in the Industrial Property Code of 10 February 2005. The norms regulating the issues of biotechnological inventions are found in separate Section IV of the Code. According to Art. 81 of the Industrial Property Code, the following items might be regarded as the objects of patenting in the case of their compliance with the requirements of novelty and inventive activity and the possibility of industrial application:

1. Biological material obtained from natural environment or using a technical process, even if it has already existed in the natural environment before that;
2. The technical process, using which the biological material is taken, recycled or used, even if it exists in the natural state;
3. Any new usage of the biological material or a technical process related to the biological material;
4. An invention which has a relation to the element extracted from the human body or obtained via any other way, using the advantages of technological process, even if its structure is identical to the composition of a natural element in the case of a specific indication and description of its function and industrial use;
5. An invention for plants or animals, which is characterized by the expression of a particular gene and not its entire genome, unless their use is restricted.

The granting of patents in the area of biotechnologies in Italy is the responsibility of the Italian Patent and Trademark Office (Italian Code of industrial property, 2005).

METHODOLOGY

One held the research of the peculiarities of the legal protection of inventions in the field of biotechnologies based on the legislation of the European countries and Ukraine using the comparative law-based, formal legal and system-structural methods. The comparative law-based method let us determine the legal framework, regarding the peculiarities of legal regulation of biotechnological inventions and their legal protection in European countries (for example, Germany, the United Kingdom, France, and Italy) as well as the settlement of the given issues at the legislative level in Ukraine. The formal legal method revealed the content of the current patent legislation in Ukraine, which regulates the legal protection of inventions in the field of biotechnologies, as well as the key aspects of the Agreement between Ukraine and the European Union in the context of the issue under study. The use of the system-structural method let us to systematize the main requirements, defined for the biotechnological inventions in order to determine their patentability and highlight the key problematic aspects of Directive 98/44/EC,

leading to an ambiguous interpretation of its norms and the existence of significant differences in the patent legislation of the member countries in the European Union.

FINDINGS AND DISCUSSIONS

The regulatory framework for the legal protection of biotechnologies at the international level includes: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 15 April 1994, the Convention on Biological Diversity, the International Convention for the Protection of New Varieties of Plants (UPOV) of 05 June 1992, Budapest Treaty on the International Recognition of the Deposit Microorganisms for the Purposes of Patent Procedure of 28 April 1977, as well as Eurasian Patent Convention of 09 September 1994 and Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological invention of July 6 1998.

It is important to note that the definition of the notion “biotechnologies” is given in Art.2 of the Convention on Biological Diversity. According to it, the notion of biotechnologies stands for any technology, related to the use of biological systems, living organisms or their derivatives for the production or strengthening of products or processes for their specific use (Convention on Biological Diversity, 1992).

The TRIPS Agreement represents the legal basis for the protection of biotechnologies of the World Trade Organization. Based on the analysis of item b. Part 3 of Art. 27, TRIPS gives member countries the right of vetoing the patenting of certain forms of life (plants and animals) and imposes the obligation to establish the patenting of particular plant varieties, micro-organisms, non-biological and microbiological processes. At the same time, it is also worth to mention the norms of Part 2 of Art. 27 of TRIPS, which provide the member countries with a possibility to veto the patenting of inventions, the obstruction of commercial use of which on their territory is necessary to protect public order or public morality, including the protection of life or health of people, animals or plants, or which is necessary to prevent significant damage of environment (EU Legislation, 1994).

An equally crucial legal document in the law of the European Union in the context of the regulation of inventions’ legal protection in the area of biotechnologies is Directive 98/44/EU of the European Parliament and of the Council of 06 July 1998, on the legal protection of biotechnological inventions (hereinafter-Directive 98/44/EC). The Art. 1 of Directive 98/44/EC clearly defines that the member countries are obliged to ensure security for biotechnological inventions according to the national patent legislation. At the same time, they can correct their national patent legislation having regard to the provisions of Directive if there is such a need. According to Art. 3 of Directive 98/44/EC, the new inventions, which involve an inventive step and the ones which are commercially applicable, are subject to patenting, even if they relate to a product, which consists of biological material including it, or to the process by means of which this natural material is produced, processed or used (European Council, 1998). Thus, according to the European Union legislation, the legal protection of inventions is carried out via their patenting.

In the context of the subject of the study, it is quite essential to draw attention to the rules defined in Art. 5 of Directive 98/44/EC, which differentiate the objects into the ones which may be patented and the group of objects, which has no relation to patented inventions due to certain peculiarities. Thus, one cannot regard the human body on different stages of its establishment

and development and the usual discovery of one of its elements, including the sequence or partial sequence of a gene, as a patent invention. The notion “patent invention,” in its turn, stands for the element extracted from the human body or obtained through any other way via a technological process, including the sequence or partial sequence of a gene, even if the structure of this element is identical to the constitution of a natural element. Herewith, the Directive 98/44/EC strictly determines the obligation to indicate in the patent application a possibility of usage of the sequence or a partial sequence of a gene for the industrial use (European Council, 1998).

The scope of protection of inventions in the area of biotechnologies is determined by Art. 8 of Directive 98/44/EC. According to this norm, the protection given by the patent for biological material, possessing specific features as a result of an invention should extend to any new biological material, obtained from this material through reproduction or breeding in the same or different form and features the same characteristics (European Council, 1998).

The Law of Ukraine “*On the Protection of Right for Inventions and Utility Models*” (of 05 December 1993) is the legal basis for regulation of the inventions’ protection, including the field of biotechnologies. Art. 1 of this law defines an invention as a result of the intellectual activity of man in any field of technology. A patent is a protecting document, which certifies priority, authorship, and the right of ownership for an invention (Law of Ukraine, 1993). The State Enterprise “*Ukrainian Intellectual Property Institute*”¹ is in charge of granting patents. This institution protects the properties of an invention.

The Association Agreement between Ukraine and the European Union of 27 June 2014 includes the prescriptions based on the content of Directive 1998/44/EC, which highlights the protection of inventions in the field of biotechnology in the Art. 221. According to the article, the protection of inventions in the area of biotechnologies is carried out in accordance with the norms of national patent legislation, but if there is such a necessity, they get responsible of adapting their patent legislation with the provisions of the Agreement (Legislation of Ukraine, 2014). The analysis of Art. 221 of the Agreement makes it possible to state that the inventions in the field of biotechnologies are given the following requirements: (1) the novelty, (2) an inventive step; (3) a possibility of industrial use. One regards a patentable invention as an element separated from the human body or produced via any other way through a technical process, including the sequence of a partial sequence of a gene, even if its structure is identical to the composition of a natural element. Herewith, one should necessarily include the industrial use of the sequence or its part into the patent application (Legislation of Ukraine, 2014).

The analysis of the provisions of the Association Agreement between Ukraine and the European Union, related to the protection of inventions in the area of biotechnologies, highlights the need for harmonization of national legislation following the requirements of European Union Law. At the same time, the process of adaptation of Ukrainian patent law to European standards should take place, paying into account the interests of both producers of biotechnological products and the interests of society.

RECOMMENDATIONS

The conducted research of the peculiarities of the legal protection of inventions in the area of biotechnologies according to the Ukrainian national legislation makes it possible to ascertain many problematic issues in this field. In particular, this refers to the lack of an effective

mechanism of cooperation between state bodies, local bodies, research institutions, and public organizations regarding the process of commercialization of innovations. One can solve this situation by harmonizing Ukrainian national legislation to the standards of European countries as well as the usage of their positive experience to create an effective mechanism for the legal protection of innovations in the field of biotechnologies.

CONCLUSION

It was quite crucial for the European Union to resolve the issues related to the legal protection of biotechnological inventions within its territories. Thus, on 06 July 1998, Directive 98/44/EU of the European Parliament and the Council on the legal protection of biotechnological inventions saw the world to offer the best solution for the problem. Thus, at the level of European Union Law, the legal protection of inventions in the area of biotechnologies is carried out via patenting.

The analysis of the provisions of the Directive 98/44/EC, regulating the division of objects into the patentable and non-patentable items, makes it possible to highlight the following important aspects. The patentability of an invention involves a mandatory condition of holding the study of a natural object only after its prior extraction out of the natural environment. The patentability of an invention is due to the isolation of an element out of its natural environment or its production via a technological process. Thus, the way of an object's separation or its acquisition through a technical process is quite essential for the patentability of the invention. It is noteworthy that the Directive 98/44/EC does not state the requirements regarding the criteria the ways of isolation or production of biotechnological products must be consistent with. The complexity of the delimitation of patentable inventions in the area of biotechnologies and non-patentable objects leads to an ambiguous interpretation of the norms defined by Directive 98/44/EC, and, therefore, one might observe significant differences in the patent laws of the member countries of the European Union.

ENDNOTE

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