

Patenting in Biotechnology

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Abstract:- The article is devoted to the study of the concepts of biotechnology and biopatent. Their scientific definitions are offered, the classification of the directions of biotechnologies is given. The paper analyzes the state of patenting of biotechnological inventions in our country. A comparative analysis of the patenting procedure in the United States and Russia is carried out. Examples of problems encountered by biotechnologists who have not patented their invention are given. The role of the patent attorney is shown. The article shows the importance of biotechnologies for the modern world and the importance of patent and legal protection of achievements in the field of biotechnologies.

Keywords:- Patent, Biotechnology, Level Of Development, Classification, Necessity, Leading Organizations, Inventions.

I. INTRODUCTION

One of the most modern and important areas of knowledge is biotechnology whose inventions significantly help to improve our standard of living. From healing the body from diseases to restoring the environment, biotechnology permeates all aspects of life.

Using nature's own tools, i.e. genes, elements, microbes, etc., biotechnology aims to improve the lives of everyone around the world. In essence, it is about harnessing nature and shaping it in order to improve our way of life.

But biotechnology is not just about using resources until they disappear. It helps the natural processes of nature by inventing both insecticides, water and air purifiers, and by creating beneficial microorganisms capable of rapid reproduction.

"Biotechnology — the application of biological processes for industrial and other purposes, primarily for the implementation of genetic manipulations with microorganisms in the production of antibiotics, hormones, etc. "[Stevenson, Waite, 2011]. The term "biotechnology" is often used as the equivalent of genetic engineering which is certainly a serious mistake. In fact, it covers a set of methods and processes related to the use of biological material (amino acids, peptides, proteins, fats, fatty and nucleic acids, cells and microorganisms) for various purposes [Rudolph, 1996].

Biotechnologists' inventions are designed to reduce the level of infectious diseases; save lives; reduce greenhouse gas emissions and produce allergen-free products.

Obviously, if you are inventing a new compound or solution to a problem you should definitely choose to get a patent. Because patents, unlike trade secrets, allow others to see and refine your ideas. In an altruistic sense, they allow you to constantly improve your technology and life.

II. MATERIALS AND METHODS

When applying for a security document, the applicant has the right to specify several groups of technologies (IPC codes) to which the patented invention belongs. Therefore, to begin with, I investigated IPC technology groups belonging to the direction of "Biotechnology". For this reason, I checked the Technology Compliance Table.

I have studied scientific articles and other literature related to this topic and analyzed the information obtained to identify the definition of a patent and the meaning of a patent in the modern world.

In order to investigate the state of patenting of biotechnologies in Russia, I applied to the Federal Service for Intellectual Property (Rospatent) and the World Intellectual Property Organization (WIPO) and also carefully reviewed the content of the Program " BIO-2020" - State Coordination Program for the Development of Biotechnology in the Russian Federation until 2020. I integrated quantitative and qualitative methods to analyse the composition of patent holders in Russia and the level of patent activity of Russian applicants in the field of biotechnology abroad.

➤ *Methodological Framework*

In this paper, I used such general scientific research methods as comparison and measurement (when evaluating the state of patenting of biotechnologies in Russia), analysis, synthesis and generalization (when studying theoretical material concerning the definition of a patent, the importance of obtaining a patent in the field of biotechnology and the role of a patent attorney in this process.

➤ *Main sections of biotechnologies*

In the course of the work on the creation of a single, generalizing classification, sections and classes of technologies were identified, and the different biotechnological methods can take place in them. According to the Technology Compliance Table, the direction of "Biotechnology" includes objects registered under the following IPC technology groups:

- C07G «of a compound of unknown structure»;
- C07K «Peptides»;
- C12M «Devices for working with enzymes or microorganisms»;

- C12N «Microorganisms or enzymes; their compositions»;
- C12P «Fermentation or enzymatic methods for the synthesis of chemical compounds or compositions or the separation of a racemic mixture into optical isomers»;
- C12Q «Measurement or testing methods using enzymes or microorganisms»;
- C12R «Coding scheme for subclasses C12C-C12Q or C12S related to microorganisms»;
- C12S "Methods using enzymes or microorganisms to isolate, separate, or purify a pre-prepared compound or composition".

➤ *Basic information about biotechnological patents*

A patent is a document that shows the exclusive right of the owner to his invention. So, the patent protects the owner from the fact that some other company will make the same invention and start selling it.

In Russia, Rospatent and FIPS are engaged in patenting. The sites have databases with already registered patents. The maximum term of validity of a patent in Russia is 25 years, with a standard term of 20 years due to the fact that clinical trials and state registration can be delayed. Moreover, from the third year of patent registration you need to pay an annual fee for its preservation.

The analysis of data on patent activity is traditionally used as one of the most important approaches to assessing the level of technological development both in general and in individual areas [Schmoch et al., 2006].

The use of patent documents makes it possible not only to obtain aggregated quantitative indicators that characterize the overall level of inventive activity but also to study its qualitative characteristics.

One of the huge obstacles to obtaining patent protection is, for instance, a fragment of coding DNA, such as the mutant BRCA gene for breast cancer, "discovered" by the American company "Myriad". There have been several furious arguments on the US Patent Office's decision to grant the company patent protection, as one of the first rules preventing such a grant is that what is found in nature does not contain an "inventive step". There were a lot of courts, and in the end they decided that the isolation of "exons" - sections of genes that actually encode proteins - from "introns" - "silent genes", was a sufficiently "inventive step" to provide them with patent protection.

Technically patents on biotechnology patents are considered to be useful. This type of patent – utility patent - is available for processes, machines, production forms, and compositions of substances. Let's look at these components in more details.

1 A process is a set or series of actions that are in a particular order or sequence. Ultimately, by following them, one thing becomes another, whether it is a state of being, a characteristic, or a property.

2 A machine is a combination of parts that perform a process. The easiest way to think about it is this: if the process is a recipe, then the machine is an oven.

3 Production: when you take raw materials and modify or assemble them according to their shape or physical properties. An example is a chair that has been joined together from wooden parts.

4 The composition of a substance is the combination of one or more substances in such a way that they form a chemical union, thus transforming them at the atomic level.

In addition, patents for useful goods must meet several criteria. That is, they must demonstrate to the Intellectual Property Office (IPO) that these inventions are new, useful from a practical point of view in a particular field, and not obvious. It should not be underestimated how important it is to emphasize the extent to which an invention improves something or solves a problem. Otherwise, they are considered too obvious or simply useless.

➤ *The importance of patenting*

Patents give inventors twenty years or even more time of exclusive rights to produce, use, and sell their inventions. Some of the most favorable aspects include:

- creating barriers to similar products on the market;
- increase in the value of the company;
- the possibility of obtaining a license income.

Research and development of any technology is usually expensive. Therefore, it is not surprising that companies suffer large losses during this entire period. They hope to eventually recoup these losses when they start selling their invention.

Fortunately, while development can be expensive, production and imitation are relatively cheap. Thus, it is imperative that the connection be patented if someone wants their connection to be reverse engineered and distributed earlier.

There is not only the financial aspect of having a monopoly on a product in the market, but also the more altruistic component of sharing knowledge with other inventors, with which to create even better ideas.

One common connection leads to another. Medications that treat the disease with potentially dangerous side effects can be improved and the risks reduced. Surgical procedures that depend on harmful doses of drugs can be replaced with something much less powerful while maintaining the same inoculation component. This is the nature of the achievements of science and technology.

Because of the very nature of biotechnological developments, patenting is the most common way to protect the intellectual property associated with them; alternative strategies are not widely used here.

Thus, a significant part of the inventions in this field relates to medicine, so the release of products produced on their basis requires a detailed description of its composition, which makes it impossible to comply with the trade secret regime.

The early release of biotechnological products to the market is also not effective: usually such production is experimental, small-scale, which in the case of premature disclosure of information allows competitors to establish the production of analogues in a short time.

➤ *The role of a patent attorney*

Patents are undoubtedly important for any inventor. Unfortunately, many people do not understand the complexity of obtaining a patent. Many people try to file patent applications on their own, which are usually rejected or, even worse, go through extremely narrow claims that allow competitors to benefit from their idea. Hence the importance of obtaining a patent attorney.

J. D. Hovener, the founder and CEO of the law firm Bold Patents Philadelphia, emphasizes: "The help of a patent attorney is necessary for an inventor to gain the benefits of widely used formulas that will prevent competitors from entering the market with something similar".

Not only for protection, but also for expediency, the assistance of a patent attorney is necessary. They have the most experience to get applications approved quickly which can sometimes take up to four years.

Obviously, this amount of time can be devastating for any business. Invest in your business today to prevent unnecessary stress and loss of profits in the future.

Biotechnology brings many benefits to the world. Therefore, we must give inventors the opportunity to benefit from their ideas as much as we do. Thus, the importance of patenting: twenty years of exclusive rights to create, use and sell their inventions on the market.

Without patenting in biotechnology, these compounds would be considered something of a trade secret-no one but the owner would know how something is made or produced. This perspective does not allow us to develop technologies, and therefore significantly improve life.

However, patents can be very difficult to navigate. Even if someone successfully obtains it on their own, larger business competitors often find ways to circumvent infringement laws and use someone else's idea for their own personal gain.

Hence the importance of getting the help of an experienced patent attorney. These are professionals who have been studying the legal language for years and know all the subtleties of an IPO. Therefore, the best choice for an inventor is a professionally verified patenting process. This route will bring the greatest profit and save you from many problems.

➤ *The state of patenting of biotechnologies in Russia*

In Russia, certain groups of biotechnologies are included in the list of critical technologies (bioengineering technologies; genomic, proteomic and postgenomic technologies; biocatalytic, biosynthetic and biosensor

technologies), and the overall development strategy is presented in the Program "BIO-2020" [BIO-2020, 2012].

The first attempts at economic and statistical analysis of the development of biotechnologies date back to the late 1980s, when surveys of scientific and technical activities in this field were implemented in a number of countries [Gokhberg et al., 2013].

The units of observation in it are biotechnological organizations that provide information about all aspects of their activities: specialization in the field of biotechnology; the volume of internal costs for research and development related to biotechnology; their effectiveness; the number and composition of employees; scientific and industrial cooperation, etc.

In a number of OECD member countries, specialized registers of biotechnology organizations are being formed, which are periodically updated and supplemented.

Integration of quantitative and qualitative methods allows to identify on the basis of public information, the most active players in the biotechnology market, which in this case is of fundamental importance: the patent monopoly sets, including on a separate DNA genomes and methods of testing without which many research and development in biotechnology (and primarily medical) cannot be implemented.

For many years, the structure of patents issued to Russian applicants for inventions in the field of "Biotechnology" is dominated by the protection documents of the Russian Federation. In the crisis of the 1990s, domestic organizations and inventors actively patented developments abroad, where during the period 1992-1997. they received almost as many patents for inventions related to biotechnology as in the next 15 years (including in countries such as Canada, Germany, Finland, Latvia etc.). Since 1996, there has been a reorientation of domestic developers to the domestic market: the number of patent applications filed with foreign patent offices has decreased, although the number of countries to which they were sent has somewhat expanded.

In general, the level of patent activity of Russian applicants in the field of biotechnology abroad remained low throughout the period under review, which may be the result of various factors: orientation to the national technology market as the dominant business strategy; lack of resources (primarily financial) required to obtain protection documents from foreign patent offices; low competitiveness of domestic developments.

In contrast to the situation abroad, domestic patent activity in the field of biotechnology has increased significantly in absolute terms over the past twenty years — from three patent publications in 1993 to 245 in 2012.

The analysis of the composition of patent holders shows the significant role played by organizations from other countries in the Russian market of biotechnological developments. However, this corresponds to the general trend of increasing patent activity in Russia by foreign applicants, which is also evident in other technological areas.

About a quarter of the biotechnology patents granted to foreign applicants belong to the United States. Among other countries, Japan, Germany, and France are very prominent in this regard.

In the structure of patents in the field of biotechnology, the leading organizations of the business sector (42.1%); the share of the public sector was 34.3%. The dominance of business is due solely to the structure of patents issued to foreign organizations, most of which (91.7%) have the status of private companies.

Among the residents, on the contrary, the undisputed leader is the public sector, represented mainly by institutes of the Russian Academy of Sciences, the Russian Academy of Medical Sciences, the Russian Academy of Agricultural Sciences and other state research centers.

In the total number of patents for biotechnological inventions obtained by domestic applicants, its share exceeded half (52.6%), while business organizations are the patent holders of only a sixth of the security documents.

Judging by the indicators of patent activity, the most numerous group is represented by developments related to the diagnosis and treatment of infectious diseases, including widespread diseases-tuberculosis, pseudotuberculosis, viral diseases. Of particular relevance in our days, was acquired by the development of a vaccine against Covid-19 (for example, Sputnik 5, ApiVakKorona).

III. RESULTS

A patent, as a type of security document granted for the results of scientific and technical activities, assigns to its owner the priority, authorship and exclusive right to use the corresponding object of intellectual property. Thus, it is guaranteeing the possibility of receiving remuneration for the resources invested in its creation. In this paper I showed the importance of registering patent, how the patent attorney can help us protect our invention from other competitors and why it is important to develop patenting in the field of biotechnology.

The most significant disadvantages of focusing exclusively on patent data when studying the field of biotechnology in Russia are related to the quality of available patent information. Open registries of the Federal Service for Intellectual Property (Rospatent) is primarily designed for patent search and identification of technological niches and is poorly adapted for analytical research. The search in the registers is carried out only according to one of three criteria — the registration number,

the date of publication, the index of the International Registration patent organization (International Patent Classification, IPC), — and the possibility of combining them is not provided by the information system.

The most reliable source of quantitative information is the World Intellectual Property Organization (WIPO) database, which contains aggregated data from all national, regional and international patent offices.

At the same time, there is no access to patent documents, and the database itself is updated with a significant delay.

Russia's contribution to the global level of patent activity in the field of biotechnology is extremely small: in 2012, out of almost 40,000 patents for inventions in this area published by all patent offices, Russian applicants accounted for less than 1%. According to this indicator, the country is significantly inferior to the leaders, ranking 18th in the world.

IV. CONCLUSION

The active development of the biotechnology sector in recent years, the research of biological objects and biomaterials, their artificial production (isolation, modification) determines significant changes in the field of intellectual property rights protection in this area. At the same time, the sphere of biological objects, biomaterials and biotechnologies has features that determine the need for a separate legal regime for their patent protection.

The active development of biotechnologies in recent years has been accompanied by an increase in the number of patent applications for biotechnological inventions, which has exceeded the average number of patents for other types of inventions [Las patentes, pilaresencialdel sector de la biotecnologia [Electronic resource] // Mundial de la PropiedadInte - lectual].

Patent currently represents the most widely used form of intellectual property protection in biotechnology, and the most controversial, due to the fact that is acting as legal title of certifying a temporary monopoly on the use of the invention in a particular territory for a specified period, preventing the manufacture, sale or use without obtaining permission from [De Robbio, A. Biobanks: Patents or open science? / A. de Robbio. – Cambridge: Woodhead Publishing, 2013, p. 26].

Biotechnological patents are used to protect technological innovation, including how it works, how it is produced, and how it can be used [Intellectual property in Biotechnology (Fact Sheet) [Electronic resource] / / European Intellectual Property Rights Helpdesk, p. 4].

The wide distribution of patents is due to the advantages offered by the system of patent law protection (in contrast to a rather frequently used in the biotechnology industry ways of legal protection as a trade secret, cross-

licensing, etc.). For example, the patent law protection allows the inventor to provide a return on investment for development, testing and implementation of innovative solutions and technologies, design, implement, and run in production may require significant financial and time resources; at the same time, the final product obtained as a result of the research – intellectual property-cannot act as a commodity in the traditional sense, but its implementation gives a real opportunity to earn income.

It is patent protection that can ensure the protection of intellectual property rights in the field of biological objects, biomaterials and biotechnologies, and at the same time make these objects available for wide use through public disclosure.

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