Legal protection of biotechnological developments

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Abstract. The current state of the biotechnology market in Russia is difficult to assess from different points of view. On the one hand, the country is significantly behind compared to the leading countries in this industry in terms of production volumes, level of market development and growth rates. On the other hand, in Russia there is a growing demand for biotechnological products from consumers. This growth is driven by factors such as an increasing population, changing healthcare needs and increased awareness of the benefits of biotechnology solutions. This growing demand represents an opportunity for both Russian and foreign biotechnology companies. However, there are a number of problems, among which are the high dependence on imports of key biotechnological products, as well as the lack of our own innovative products in this area. To strengthen the competitiveness of the biotechnology market and ensure domestic innovative products, measures are needed to stimulate investment in research and development, promote research and educational institutions, create a supportive regulatory environment and develop human capital in this area.

1 Introduction

Legal protection is of utmost importance in the establishment and advancement of a biotechnological enterprise. The biotechnology industry has unique characteristics that distinguish the legal protection of biotechnological developments from other domains. Currently, two primary methods are employed to safeguard biotechnological developments:

1. Patenting: This method is typically utilized when the biotechnological development involves novel and non-obvious inventions. Patenting ensures exclusive rights to the invention, preventing others from using, making, or selling the protected innovation. In the biotechnology context, patent protection is often more appealing due to the substantial investment, time, and effort required for research, development, production, and implementation. A patent provides robust guarantees, such as safeguarding against the unauthorized replication of the development, financial support through product demand and cost coverage, and the capacity to continue research and development.

2. Know-How: The know-how approach is employed when a biotechnological development comprises components or compositions that are already known but are

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combined in specific proportions. It is feasible to sidestep a patent by altering the quantitative composition of components. Know-how is also appropriate when it is challenging to ascertain the precise processes involved in producing a particular biotechnological product. In scenarios where a similar biotechnology has already been patented, the holder of the know-how retains prior usage rights. This enables them to sustain production volumes and sell the product within a designated territory without expanding production capacity [1].

In general, employing a patent regime for biotechnological developments is considered more advantageous from various standpoints. Biotechnological endeavors entail lengthy processes and substantial investments. Patents offer comprehensive protections, ensuring the safeguarding of innovations, covering development costs, facilitating product introduction, and enabling further research.

2 Research Methodology

It's important to recognize that Russia has some unique features concerning the patent holders in biotechnology:

- The number of protection documents issued by Rospatent to foreign patent holders is three times higher than those issued to Russian applicants.
- State-owned enterprises hold the majority of patents for biotechnological developments in the Russian Federation, often with the Russian Federation as a co-owner. This arrangement can pose challenges to the growth of biotechnology.
- The number of patent applications for genuinely new biotechnological developments is significantly lower than the number of patents related to the main invention (generics). This discrepancy contradicts the goals outlined in the "Comprehensive Development of Biotechnologies in the Russian Federation for the Period Until 2020" program.

For a biotechnological innovation to be considered patentable, it must meet several criteria, including novelty, inventive step, and industrial applicability. However, there are specific issues and debates in the biotechnology field [2]:

- The novelty criterion for biotechnologies can be challenging, as some natural products may have compositions similar to biotechnological ones. Experts need to distinguish between naturally occurring genes and artificially created ones, and whether these genes serve therapeutic purposes. Modifying natural human genes can be contentious from an ethical standpoint.
- The inventive step criterion considers the extent to which a scientist contributed to the creation, modification, extraction, or transformation of an object. If the author isolates an object known to the biotechnological community but creatively contributes to its composition, this can be patentable. Separating the biotechnology from the biotechnological product becomes a critical factor.
- The "industrial applicability" criterion, which is a vital aspect of patentability, lacks clear definition in the current legislation of the Russian Federation. However, Directive 98/44/EC of the European Parliament provides guidance on the legal protection of biotechnological inventions. This criterion encompasses various purposes for patenting a biotechnological product, including industrial, scientific, commercial, diagnostic, and therapeutic applications.

3 Results and Discussions

The legal protection of biotechnological developments plays a critical role and comes with distinct considerations, particularly in the realm of biotechnology. Two primary methods

for safeguarding these developments are through patents and know-how. The choice between these approaches depends on the nature of the biotechnological development. Know-how is commonly used when the development is composed of known elements in certain proportions, allowing the possibility to evade patents by altering the ingredient ratios. This approach is also relevant when the precise processes used to create a particular biotechnological product are hard to determine. In instances where a similar biotechnology is already patented, know-how offers the advantage of prior use rights, allowing the maintenance of production and sales without expanding production volumes in specific territories. Nevertheless, the patent regime is generally regarded as more advantageous for biotechnological innovations [3]. The uniqueness of biotechnology stems from its long and resource-intensive development process, which necessitates substantial investments. Patents offer crucial safeguards, protecting the innovation from being copied, covering development costs and product introduction, enabling further research, and more.

When it comes to patent holders in Russia, some distinctive features exist:

1. A considerably higher number of protection documents are issued by Rospatent to foreign patent holders in comparison to Russian applicants.

2. State-owned enterprises in the Russian Federation hold the majority of patents for biotechnological developments, and the Russian Federation is often a co-owner. This arrangement can pose challenges for biotechnology's growth.

3. The number of patent applications for genuinely new biotechnological developments is significantly lower than the number of patents related to the main invention (generics). This situation contradicts the objectives set in the "Comprehensive Development of Biotechnologies in the Russian Federation for the Period Until 2020" program.

To qualify for patent protection, a biotechnology must satisfy specific criteria, including novelty, inventive step, and industrial applicability [4]. Nevertheless, there are debates and issues related to these criteria in biotechnology:

1. The novelty criterion can be challenging for biotechnologies since some natural products may have compositions similar to biotechnological ones. Experts must differentiate between naturally occurring genes and artificially created ones, particularly if they serve therapeutic purposes. Modifying natural human genes can raise ethical concerns.

2. The inventive step criterion considers the degree of a scientist's involvement in the creation, modification, extraction, or transformation of an object. If the author creatively contributes to the composition of an object known to the biotechnological community, the development can be patentable

3. The "industrial applicability" criterion lacks a clear definition in the current Russian legislation. Directive 98/44/EC of the European Parliament provides guidance on the legal protection of biotechnological inventions. This criterion encompasses various purposes for patenting a biotechnological product, including industrial, scientific, commercial, diagnostic, and therapeutic applications.

In summary, the legal protection of biotechnological developments in Russia has distinct characteristics [6]. The practice of applying patent protection for biotechnology is not well-established, and there is notable inconsistency in the interpretation of laws. Additionally, there is a lack of sufficient means and methods of implementation, along with a somewhat narrow approach to characterizing certain types of biotechnology.

Biotechnology requires a robust infrastructure, especially concerning the conditions at enterprises for conducting preclinical and clinical trials in accordance with international standards like GLP, GCP, and GMP:

- GLP (Good Laboratory Practice):This quality system covers the conditions and organizational processes for non-clinical studies concerning health and environmental safety [7]. The system has specific requirements for research organization, personnel, premises, experimental subjects (if needed), laboratory equipment, testing methods, data

registration, and the control service. In Russia, the national equivalent of the GLP system is the GOST 33044-2014 "Principles of Good Laboratory Practice" standard.

- GCP (Good Clinical Practice):It is an international standard for planning and conducting research involving human participants, ensuring the reliability of clinical trial results, the safety of participants, and protection of their rights. In Russia, the national equivalent of the GCP system is the GOST 52379-2009 standard "Rules for the Production and Quality Control of Medicines."

- GMP (Good Manufacturing Practice): This international standard outlines requirements for the production and quality control of biotechnological drugs, quality control of developments, and special requirements for the production of active pharmaceutical substances and specific types of medicines. In Russia, the national equivalent of the GMP system is the GOST R 52249-2009 standard "Rules for the Production and Quality Control of Biotechnological and Medicinal Products."

Currently, no biotechnology enterprise in Russia can conduct comprehensive tests recognized in the international market, including the markets of thirty-five developed and developing OECD countries [8]. These limitations restrict the sales markets for innovative biotechnological products to the markets of the customs union countries and some CIS countries.

In response, most Russian biotechnological enterprises have shifted towards adopting the international Good Manufacturing Practice (GMP) standard. This transition aims to enhance product quality and align with international standards for marketing products abroad. The GMP standard entails several features and requirements for biotechnological enterprises, encompassing aspects such as buildings and premises, equipment, production processes, quality control, and validation. (See Appendix 1 for specific details).

The implementation of a new biotechnological production process typically begins with laboratory-scale performance testing [9]. If these initial tests prove successful, a pilot plant is established using common laboratory equipment. This pilot plant employs a fermenter ranging from 2 to 200 cubic decimeters to carry out the process. Optimized physical conditions and nutrient requirements are determined to maximize product yield.

For a full-scale production expansion, which may involve volumes in the thousands of cubic decimeters, various additional factors and considerations come into play. However, it's essential to note that in some instances, such a transition might not be feasible. Some of the most crucial factors to consider include:

- Maintaining sterile conditions.
- Addressing physical factors such as mixing, medium aeration, and preventing overheating.
- Ensuring effective aeration for optimal oxygen access to cultures, potentially using a diffuser for air supply. This may include incorporating reflective baffles into fermenter walls to extend the time air bubbles take to traverse the vessel, enhancing turbulence and dissolution efficiency in water [10].
- Managing foam through the use of defoamers to reduce foaming generated by agitation and aeration.
- Implementing a water circulation system for cooling.
- Installing complex monitoring and control systems.
- Maintaining precise control over conditions.
- Anticipating the economic consequences in case of defects or accidents.
- Managing the labor-intensive tasks of water delivery and sterilization in large quantities.
- Securing readily available, stable, easy-to-handle, and storable starting materials with minimal chemical changes and microbial contamination.
- Addressing the possibility of strains of microorganisms easily reverting.

- Ensuring safety when handling powdered substances.
- Utilizing materials that resist corrosion and withstand sterilization with high-pressure steam while being non-toxic to microorganisms [11].
- Recognizing additional risks associated with the use of genetically modified organisms.

4 Conclusions

Here are several proposals aimed at fostering the development of the biotechnology sector in Russia:

1. Strengthen Organizations:Establish organizations responsible for biotechnology development and ensure ongoing monitoring of biotechnology companies' activities.
2. Special Status for Enterprises:Grant biotechnological enterprises a specific status that enables them to receive tax and customs benefits, which can incentivize growth in the sector.
3. Anchor Projects:Identify and support "anchor" projects through competitive selection in various biotechnology fields. These projects can serve as industry development drivers.
4. Support Funds Creation:Facilitate the establishment of funds that focus on industrial, agro-, and environmental biotechnologies. These funds can provide financial support to biotech ventures.
5. Prioritize Breakthrough Drugs:Develop systems that prioritize the research and development of breakthrough drugs, encouraging innovation in the pharmaceutical biotechnology sub-sector.
6. Tax Benefits:Create tax preference systems for projects conducted by both state scientific and educational institutions and private businesses in the field of biotechnology.
7. Biodegradable Standards:Develop standards for plastic packaging, mandating a certain proportion of biodegradable materials. This promotes the use of more sustainable packaging in the industry.
8. Chemical Pesticide Restrictions:Implement restrictions on the use of chemical crop protection products to encourage the adoption of more sustainable and environmentally friendly practices in agriculture.

These proposals aim to address the existing problems in Russia's biotechnology sector, which include significant import dependence on critical biotechnological products like feed additives and drugs, and a lack of domestically produced biotech products. By implementing these measures, Russia can advance its biotechnology industry, reduce dependency on imports, and foster innovation in the sector.

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