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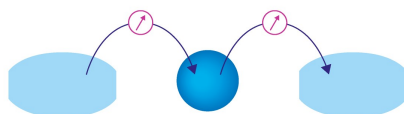
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Current State and Future Prospects of Biotechnology in the Russian Federation

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Abstract. In this article, the current state of the biotechnology market in Russia and access to its development prospects were evaluated. Russian state programs for the development of biotechnology were stated. The growth rates of the industry in Russia and the world are analyzed.

INTRODUCTION

According to the Russian national standard GOST R 57095 [1], biotechnology is “the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services”. This industry is a mixture of modern knowledge from genetics, molecular biology, biochemistry, microbiology, bioinformatics, and its practical applications for creating innovative products.

Today, biotechnology is one of the most dynamically growing areas of science and technology. Potential benefits from its use can be found in the following fields: healthcare, development of new materials and alternative fuels, agriculture, food industry, environmental protection, etc.

Biotechnology is one of the leading trends in the 21st century due to its wide scope of application and huge space for further development. It is safe to say that conducting research & development (R&D) in the field of biotechnology, providing financial support to biotech companies, and ensuring public access to their products are key tasks for any country in the world.

At the moment, the Russian Federation is not among the world leaders in the biotechnology market, but this situation may change in the future. Biopharmaceutics is considered one of the most developed biotechnological industries in our country; the most promising areas are bioenergy, industrial, food and environmental biotechnology [2]. In this article, the main trends in the development of the biotechnology market in Russia and the world are examined.

BIOTECHNOLOGY IN THE WORLD

The biotechnological industry is strategically important and one of the priority directions for the development of bioeconomics, both in Russia and in the world. In recent years there has been a steady rise in this industry around the world. The global biotechnology market totaled \$ 449 billion in 2019 and is projected to reach \$ 729 billion in 2025. The average annual growth rate varied in different regions and generally did not exceed 7-8% over the past 5 years [3]. It is considered that biotechnology can be used as a good indicator of a state's international competitiveness in a high-technology and knowledge-intensive area [4].

In 2016, Scientific American published the top biotech countries in the world (Fig. 1). Various indicators were evaluated in seven categories: Productivity, Intellectual Property (IP) Protection, Intensity, Enterprise Support,

Education/Workforce, Foundations, and Policy & Stability. Each country's performance for individual components was evaluated on a scale from 0 to 10 [5].

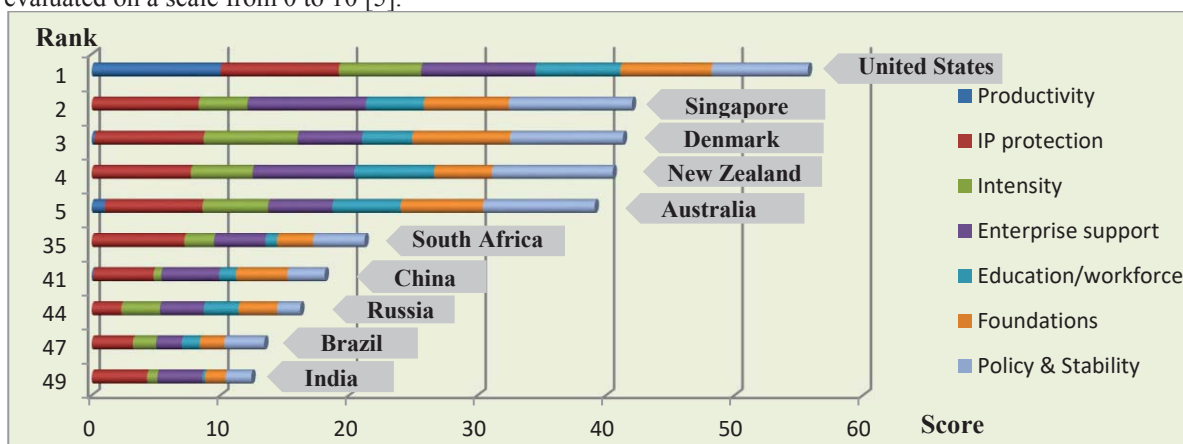


FIGURE 1. Top biotech countries in the world.

The top five are the United States, Singapore, Denmark, New Zealand, and Australia.

Russia took the 44th place, improving its position by 3 places compared to 2015. Also, Russia ranked 9th in the "Intensity" category, which evaluates efforts in the field of biotechnological innovations. This indicates that Russia is trying to become a leader in the field of biotechnology and making a lot of actions for it.

BIOTECHNOLOGY IN THE RUSSIAN FEDERATION

The main document defining the vector of development of biotechnology in Russia is the State Coordination Program for the Development of Biotechnology in the Russian Federation until 2020 (BIO 2020). The goals of the program are:

- Boosting the development of certain areas of Biomedicine, agricultural biotechnology, industrial biotechnology, and bioenergy.
- Reaching the level of production of biotechnological products in the amount of about 1% of GDP by 2020 and 3% of GDP by 2030.
- Increase in the volume of production of biotechnological products by 33 times.

Adopted in 2012, it is a long-term formation strategy of modern bioeconomy in Russia. Along with it, the technology platform "BioTech2030" was formed, designed to unite industrial, educational and scientific–research institutes for cooperation in the field of bioindustry. The BIO2020 program was followed by several high-level documents and decisions in the areas of biotechnology and bioeconomy [6]. Some of them are shown in Table 1.

TABLE 1. Documents related to biotechnology development in the Russian Federation [6].

Document	Year of Acceptance
State Coordination Program for the Development of Biotechnology in the Russian Federation until 2020	2012
The state program of development of agricultural industry and regulation of the markets of agricultural products, raw materials and food for 2013–2020	2012
“Industrial biotechnologies” subprogram of the state program “Development of Industry and Increase of Its Competitive ability till 2020”	2012
Prognosis of scientific and technological development of agriculture of the Russian Federation (to 2030), report of Russian Minister of Agriculture Alexander Tkachyov	2016
The plan of measures (“road map”) “Development of biotechnologies and genetic engineering” in 2018–2020	2018
Federal scientific-technical program for genetic technologies development in 2019–2027	2019

By decree of the Government of the Russian Federation No. 898 of July 13, 2019, the Government Coordination Council for the development of biotechnologies was established. This was done to improve the interaction of government authorities and scientific institutions when considering issues related to the implementation of state policy in the field of biotechnology.

Recent studies have shown that the growth of the domestic biotech market is lower than indicated in the BIO2020 program. According to data for 2015, market volume amounted to 195 billion rubles, which is half of the planned 400 billion rubles. In 2018, it amounted to just over 250 billion rubles, so in the period from 2015 to 2018 biotech in Russia grew by 30%. By 2020, the market is projected to grow to 262 billion rubles instead of the planned 1 trillion rubles [7].

There are also over-fulfilled tasks with regards to the roadmap “Development of biotechnologies and genetic engineering”. By 2020, the production of industrial biotechnologies is 17 billion rubles against the planned 14.8 billion rubles. The export of domestic biotechnological products also exceeded the target indicators. In 2015, the volume of its deliveries abroad amounted to 14 billion rubles or 29% of domestic production. The export of domestic biotechnological products is expected to reach 26 billion rubles in Russia in 2020 [7].

Patent Activity

Patents are key indicators of innovative products since patent indicators reflect the results of inventive activities of countries, regions, technologies, firms, etc. They are also used to track the level of dissemination of knowledge in technological fields, countries, sectors, firms, etc., as well as the level of internationalization of innovation. Patent indicators can be used to measure R&D output, performance, structure, and development of a technology/industry [8]. Patent activity analysis is a good method for evaluating biotechnology indicators such as knowledge dissemination and research direction [9].

The international patent classification (IPC) is used to separate patents by application area. It is a hierarchical system of alphabetic and numeric indexes that allows you to assign patents to various fields of technology. Currently, biotechnology is not allocated to a separate class of IPC, which means that developments in this area can fall into a fairly large range of sections, groups, and subgroups.

In our study, the database of the World Intellectual Property Organization (WIPO) was used as the research base, which contains data from all national, regional, and international patent offices. For the implementation of patent counts “Methodology to identify biotechnology patents” by OECD was used [9]. The essence of this method is a double search for the most associated with biotechnology IPC codes and keywords in the description and text of the patent. This approach provides a good selection and reduces the percentage of errors. Next, the results are analyzed (a top-down approach) and documents with completely missing keywords and/or specified IPC codes are filtered out. The following keywords were used: “biotechnology”, “biotechnologies”, “molecular biology”, “biochemistry”, “genetics”, “microbiology”, “biomedicine”, “biopharmaceutics,” and “bio pharmacy”. The IPC codes related to biotechnology were taken unchanged from the above methodology. The search was conducted for the period 2013-2018. The results of the study are shown in Fig. 2.

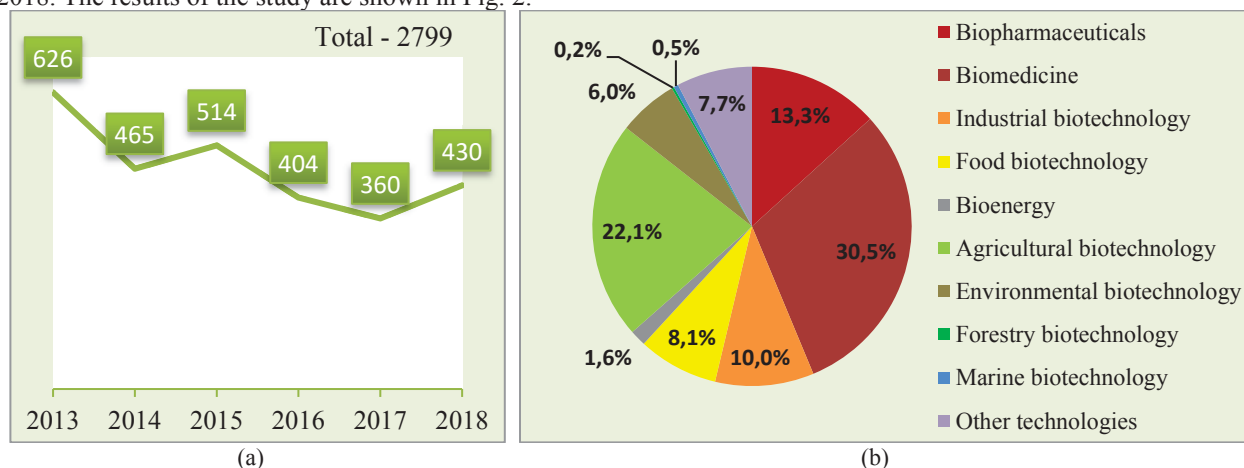


FIGURE 2. (a) Number of patents applied in the Russian Federation in the biotechnology field; (b) Percentage distribution of patents applied in the Russian Federation in the biotechnology field for 2018.

Overall, the number of patents from 2013 to 2018 in the field of biotechnology decreased from 626 to 430. This situation may be due to the low interest of companies and investors and a long application review period (up to several years), which leads to the loss of relevance of the invention. However, there is an increase in the share of biotechnological inventions in the total number of published patents: from 1.4% in 2012 to 1.7% in 2018 [10].

The next stage of the study was to estimate the percentage distribution of patents in 2018 in the field of biotechnology (Fig.2b). For the analysis, titles, abstracts, and full texts of documents were used. The inventions were assigned to the main areas of biotechnology identified in BIO-2020. Patents that contained information about General technologies aimed at the development of biotechnology were classified in a separate category “Other technologies”. This category included inventions related to the CRISPR/Cas9 system, improved PCR variants, new vectors, etc.

The largest number of patents relates to biomedicine, biopharmaceuticals, agricultural, industrial, and food biotechnology.

From 2007, the Russian Patent Office (Rospatent) and the Federal Institute of industrial property (FIPS) began compiling lists of the best inventions of the year. One hundred of the most interesting inventions are selected from the list of “Promising inventions”, which are then published in the public domain [11]. In 2018, the section “Biotechnologies” was added to this list. Until this time, biotechnological inventions were mostly described in the sections “Biochemistry”, “Pharmaceuticals” and “Food industry and agriculture”. For the period 2015 – the first half of 2020, 23 patents in the field of biotechnology were presented in the “Top 100 inventions of the year” (average annual value: 4.6). Table 2 shows some of these patents.

TABLE 2. Several patents in the field of biotechnology which are included in the "Top 100 inventions of the year" for the period 2018 – the first half of 2020

Title	Description	Area of biotechnology	Patent number RU
Method for identification of genetic markers of telomere length regulation	Method for detecting genetic factors (genes) determining cell-telomere DNA-structure functioning, which in turn determines the eukaryote cell life span. Possibility of improving the quality of human life by enabling the possibility of predicting the development of diseases associated with the aging process.	Biomedicine	2684702
Monoclonal antibody, linking with the Ebola virus glycoprotein	The invention allows preparing new monoclonal antibodies selectively binding the Ebola virus glycoprotein as well as an isolated DNA fragment encoding the light and heavy chain regions of the said antibody, and an antigen-binding fragment of the said monoclonal antibody.	Biopharmaceuticals	2644334
<i>Pseudoalteromonas Arctica</i> strain for the decomposition of oil and oil products	The invention provides for purification of water areas of water bodies, shoreline from oil and oil products at a temperature of +20 to -2½ °C, and salinity 30±10 g/l in nutrient-poor conditions.	Environmental biotechnology	2703142
Biological sensor based on graphene oxide	The method of producing a biological sensor based on graphene oxide involves forming a graphene-containing material on a film substrate, patterning the obtained film to form a conducting channel, and modifying the surface of the film with chemical compounds. The invention allows creating high-sensitivity biosensor with the possibility of multiple measurements and integration into personal devices of health state monitoring.	Nano biotechnology	2697701

Prospects

Biotechnology is considered one of the most important and rapidly developing areas of science and technology. Most world experts agree that the growth rate of the industry will remain high soon [12].

By 2025, the market is expected to grow to 325 billion rubles, higher by 29% compared to 2018. The growth of the Russian biotechnology market is largely due to the rapid development of the biomedical and biopharmaceutical areas. The total volume growth in these segments in 2015-2020 will amount to 35 billion rubles. Further growth of the biomedical segment is expected due to new analogs of original drugs and technologies, including those developed in Russia [7].

The monoclonal antibody (MCA) segment is one of the fastest-growing markets in the field of biopharmaceuticals now, Russia included. The first domestic original drug based on monoclonal antibodies was registered in Russia in 2019 [13].

The second-largest segment of the Russian biotechnological market is agriculture. By 2025, the market for agricultural biotechnologies will increase to about 112 billion rubles. Feed supplements are the main drivers of this area [7].

Back in 2012, the BIO2020 program was considered ambitious [4]. The forecasts were based on very high growth rates of the global biotechnology industry (up to 30% per year), which were not fully justified. Nevertheless, the average annual growth rate of the Russian biotechnology market is currently ahead of the global growth rate. Although most of the goals were not achieved, the government's efforts have helped to accelerate the development of the biotechnology market in Russia and prepare platforms for its further growth. The creation of a new long-term program until 2030 will allow the state to approach the original main goal, which is making Russia one of the leaders in the biotechnological industry.

CONCLUSION

Over the past 10 years, the field of biotechnology in Russia has undergone some changes. The long-term national program BIO–2020 was adopted along with several documents that regulate the development of the bioindustry. At the same time, the most developed areas of biotechnology in Russia are still biopharmaceuticals and biomedicine, along with agricultural biotechnology. This situation is also reflected in patent distribution. The average annual growth rate of the Russian biotechnology market is currently ahead of the global growth rate. However, Russia is yet one of the top biotech countries.

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