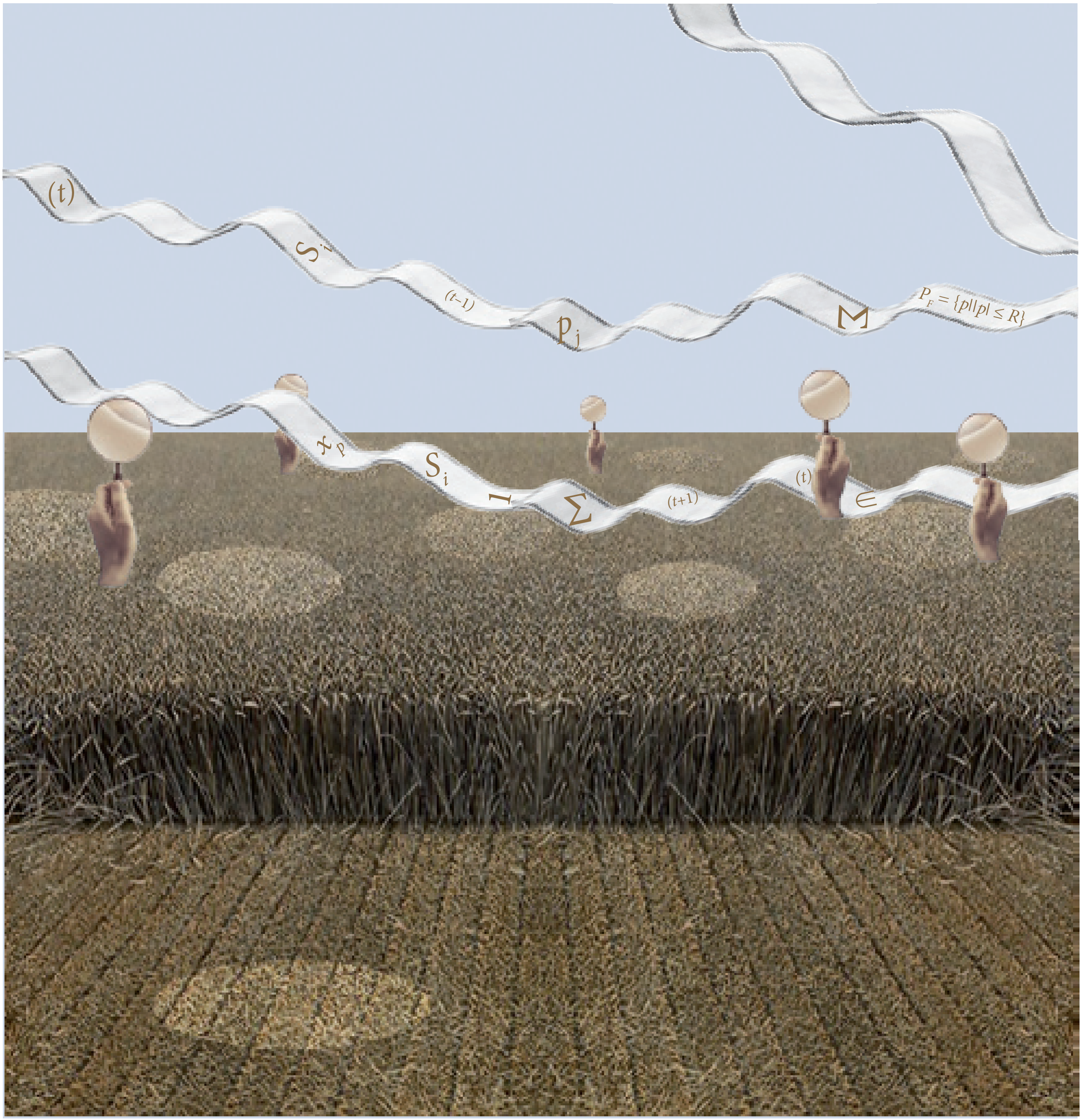
Patent Activity in Biotechnology

Ekaterina Streltsova



The significance of biotechnologies for solving global problems and making social and economic progress is recognized in many countries, including Russia. Managing this field requires up-to-date and reliable information about technological trends and the emergence and diffusion of innovations.

This paper examines the possibility of applying a patent-based methodological approach to the study of biotechnologies in Russia, and assesses its explanatory potential.

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patent analysis;
patent activity.

Today developing biotechnologies, expanding the market for biotechnological products, and increasing demand for biotechnologies are among government priorities in many countries. For example, in the United States, which represents the largest market for biotechnologies in the world – both in terms of the volume of investments as well as the scale of production [Ernst&Young, 2013] - the federal and local governments are stimulating scientific research and production in this field, for years establishing special tax treatment for biotechnology organizations, promoting the creation of technology parks and venture funds, and providing guarantees for loans [*Butcher*, 2009]. Canada has taken a number of measures to attract venture capital (including foreign venture capital) for developing biotechnologies [*Gwynne, Page,* 1999]. In European countries, six of which (France, Spain, Germany, Great Britain, Switzerland, and the Netherlands) are among the ten global leaders in terms of the number of biotechnology organizations [OECD, 2011], strategic significance is now given to building bioeconomics, based on a more rational and efficient utilization of resources, with the application of biotechnologies [European Commission, 2012; Horizon 2020].

In Russia, individual groups of biotechnologies are included in the list of critical technologies (bioengineering technology; genetic, proteomic, and postgenomic technologies; biocatalytic, biosynthetic, and biosensor technologies)[1], and the overall development strategy is given in Program "BIO – 2020" [BIO – 2020, 2012].

Such attention to the field of biotechnology is associated with its role in solving large-scale challenges in ecology, energy, and public health. Biotechnological innovations have a revolutionary impact on the development of pharmaceuticals and medicine, particularly methods to prevent and treat such socially significant illnesses as Alzheimer's, tuberculosis, diabetes, cancer, and HIV [*Rao*, 2012]. The use of biotechnologies makes it possible to raise crop yields, animal productivity, and food production, which are especially important in a context of constant global population growth. The development of biotechnology also favorably influences the environment, reduces the negative effects of humans on the environment, and helps eliminate the consequences of manmade disasters and pollution of the soil, water, and atmosphere.

The realization of these biotechnology possibilities as well as the impressive investments in their development require the creation of a well-grounded approach to regulating this field and adoption of balanced management decisions, which is impossible without complete and reliable information about its current state, particularly the factors preventing further progress. Two questions inevitably arise when addressing this matter. First, how can we best define the object of analysis? Second, what are appropriate methods to study the object of analysis? This paper proposes potential answers to these questions: it attempts to outline the boundaries of the biotechnology field and describe a methodology for its study using patent analysis. As a result, it has become possible to assess the technological trends that reflect the long-term picture of the biotechnology field in Russia.

The biotechnology field: what is it?

The starting point for the development of a methodology to analyze the state of this field is a clear understanding of the term "biotechnology," which in turn serves as a criterion for a subsequent survey of observations and the assignment of objects (organizations, scientific research results, goods and services) to biotechnology categories. This procedure is a matter of principle: Research conducted by Canada's national statistics agency (*Statistics Canada*) has shown that the results of statistical surveying of the biotechnology field change dramatically even with insignificant changes in the definition being used [*Chaturvedi*, 2003].

The concept of "biotechnology", encountered everywhere today and repeated in many publications and government documents, has a multitude of meanings (Table 1). A basic definition understandable to readers who are not experts in the field can be found in any encyclopedic dictionary: biotechnology is the

Modern biotechnologies and the method of recombinant DNA

The phase of active development of modern biotechnologies began in 1973 after the development of recombinant DNA technology by Herbert W. Boyer and Stanley N. Cohen [*Demaine, Fellmeth,* 2002]. Its main purpose - to transfer to a host organism characteristics that are inherent to a donor organism by isolating a gene from the donor's DNA and recombining it in vitro in the host organism's DNA and then integrating it in its cells [*Hughes,* 2001]. The creation of insulin was the earliest achievement of recombinant DNA technology: previously diabetes patients were treated with insulin extracted from the pancreases of cows or pigs; the recombinant technology made it possible to isolate the insulin gene from human DNA, transplant it into plasmids, and then introduce the altered plasmids into microorganisms capable of producing insulin. This made it possible to obtain a large amount of insulin from colonies of such microorganisms at a significantly reduced cost. Other achievements of recombinant DNA technology include the creation of several types of interferons required to treat cancer and leukemia, the synthesis of human growth hormone to treat pituitary dwarfism, etc. It is worth noting that the use of recombinant DNA technology is not limited to the medical and pharmaceutical fields – it also finds application in agriculture and industry [*Ko,* 1992].

[1] List of Critical Technologies of the Russian Federation (approved by Order No. 899 of the President of the Russian Federation of July 7, 2011).

Table 1. **Basic definitions of biotechnologies**

Biotechnology is a collective noun for the application of biological organisms, systems or processes to manufacturing and service industries.
• Integrated use of biochemistry, microbiology, and engineering sciences in order to achieve technological (industrial) application capabilities of microorganisms, cultured tissue and parts thereof
• A technology using biological phenomena for copying and manufacturing various kinds of useful substances
• The application of scientific and engineering principles to process materials by biological agents to provide goods and services
• The science of the production processes based on the action of microorganisms and their active components and of production processes involving the use of cells and tissues from higher organisms. However, biotechnology is not a separate scientific field. Rather it combines the effects of microbiology, biochemistry, molecular biology, cellular biology, phytobiology, immunology, protein engineering, enzymology, mammalian cell culture, and other sciences
• Really no more than a name given to a set of techniques and processes
• The use of living organisms and their components in agriculture, food and other industrial processes
• The deciphering and use of biological knowledge
• The application of our knowledge and understanding of biology to meet practical needs

Source: [OECD, 2005].

application of biological processes for industrial and other purposes, chiefly to perform genetic manipulations with microorganisms during the production of antibiotics, hormones, etc. [*Stevenson, Waite*, 2011]. The term "biotechnology" is often used as a synonym of genetic engineering, which is an unqualified error. In reality, it encompasses an entire array of methods and processes associated with the use of biological material (amino acids, peptides, proteins, fats, fatty and nucleic acids, cells, and microorganisms) for various purposes [*Rudolph*, 1996].

Consequently, many experts assert that the concept of "biotechnolog*y*" does not exist and that the only correct solution is to use the plural form of the word – "biotechnolog*ies*". To speak of the biotechnology industry as a separate sector is also erroneous – biotechnologies find application in various fields: food production, pharmaceuticals, forestry, and more.

Obviously, the basic definition we have considered is inadequate for analytical purposes because it does not allow us to separate biotechnological developments and products from objects belonging to other fields. This problem is solved by internationally-accepted single and list-based conventional definitions of biotechnologies recommended by the Organization for Economic Cooperation and Development (OECD) for conducting statistical surveys [*Gokhberg*, 2012]. According to the single definition, biotechnologies are the sum total of the approaches and methods of applying 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 [*OECD*, 2005]. This definition has been intentionally expanded. It encompasses not only all modern forms of biotechnologies but also many types of activities - traditional and transitional - that are gradually transforming under their influence. The list-based definition supplements the general definition, unfolding the field's subject matter and detailing it based on groups of biotechnologies (Table 2). Such an approach allows us - in a first approximation - to mark out the boundaries of the biotechnology field and operationalize the basic definition for the purpose of statistical measurement and analysis [*Gokhberg et al.*, 2013].

Statistical surveying in the biotechnology field

The first attempts at economic and statistical analysis of the development of biotechnologies took place in 1980, when scientific and technical investigations in this field were undertaken [*Gokhberg et al.*, 2013]. Ten years later, the national statistics agencies of Canada, New Zealand, and France conducted special investigations of industrial organizations whose activities were related to the development and use of biotechnologies [*Ibid.*]. At present the most widespread practice (in many countries including Australia, Great Britain, Germany, Israel, Italy, and Canada) is statistical inquiry, using a methodology developed by the OECD. The methodology's units of observation are biotechnology firms[2] that provide information about all aspects of their activities: specializations within the biotechnology field; the amount of internal expenditures on research and development related to biotechnologies; the productivity, number, and structure of employees, scientific and industrial collaboration, etc.

Statistical inquiry requires significant resources of time and money. Above all, this is a result of the search for and selection of biotechnology firms, which are extremely difficult challenges because they are not assigned to an independent category in existing classifications of business activities: biotechnologies may be developed and used by organizations belonging to different sectors, and identifying them is a methodological problem that lacks a concrete solution due to the very nature of biotechnologies as an inter-industry and interdisciplinary ("horizontal") technological field. Additionally, biotechnology companies are often small firms, many of which are startups and not included in standard statistical measurements. These circumstances greatly complicate the search for and

[2] Biotechnology firms («biotechnology-active firms») are enterprises and scientific organizations whose activities include the development and/or use of at least one biotechnology (according to the list-based definition considered above) to produce goods and/or provide services and to perform scientific research and development [*OECD*, 2005].

Table 2. **List-based definition of biotechnologies**

Biotechnology group	Subject matter
DNA/RNA	Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/ synthesis/amplification, gene expression profiling, and use of antisense technology
Proteins and other molecules	Sequencing/synthesis/engineering of protein and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics; protein isolation and purification, signaling, identification of cell receptors
Cell and tissue culture and engineering	Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation
Process biotechnology techniques	Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulfurization, bioremediation, biofilteration, and phytoremediation
Genes and RNA vectors	Gene therapy, viral vectors
Bioinformatics	Creation of databases of genomes, protein sequences; modeling complex biological processes, including systems biology
Nanobiotechnology	Applies the tools and processes of nano/microfabrication to build devices for studying bio systems and application in drug delivery, diagnostics, etc.

Source: [OECD, 2005].

sampling of responding organizations. In a number of countries belonging to the OECD, special registries of biotechnology firms are being created, which are periodically updated and added to. They are based on different sources of information, including materials from foundations and programs supporting science and innovation, tax agencies, business associations, etc. However this does not guarantee completeness, relevance for the purposes of the statistical survey (possession of the characteristics of a biotechnology firm), or representativeness (representation of all groups and categories of such organizations).

In Russia, efforts to develop registries of biotechnology firms began relatively recently and are fragmented and uncoordinated. The cost of these efforts justifies a search for other ways to investigate the field. One such alternative approach is patent analysis, which makes it possible to assess the present state of biotechnologies in Russia and the direction of their technological development.

Methodological principles of patent analysis in the biotechnology field

Analysis of data about patent activity has traditionally been used as one of the most important approaches to evaluating the level of technological development, both overall as well as in individual areas [*Schmoch, Rammer, Legler*, 2006]. As a type of document granted to protect the results of scientific and technical activities, a patent secures for its holder the priority, authorship, and exclusive right to use the corresponding object of intellectual property, thus guaranteeing the opportunity to receive a reward for the investments made in creating the asset. Neither can we disregard the significance of patents as a unique source of technical information [*Gokhberg*, 2003]. Thus, patent statistics (for example, the number of patent applications or patents granted) may be considered a reflection of the actual level of inventive activity in various segments of the technology market. In view of several circumstances, such an approach is entirely justified to assess trends in the development of biotechnologies.

Due to the very nature of biotechnological innovations, the most widely used method of protecting the associated intellectual property is specifically by securing a patent; alternative strategies are not widely employed here. For example, a significant portion of inventions in biotechnology relate to medicine; as a result releasing products requires a detailed list of their ingredients, which makes it impossible to maintain a trade secret. Rapid production is not effective either: in many instances such products are experimental and are produced in small batches, which in the event of premature disclosure of information allows competitors to release an identical product in a short period of time. Advertising, which in other sectors helps increase trust in the manufacturer and gives it a certain advantage over its competitors, by no means always produces the desired result here: groups of consumers of biotechnological products (especially in such narrow fields as cosmetics, maritime biotechnologies, and bioenergy) are highly specific and rely not so much on brand trust as on technical knowledge and product quality.

Analyzing the state of the biotechnology field in Russia using patent analysis undoubtedly has both merits and shortcomings. First, the use of patent documents not only makes it possible to receive aggregated quantitative data that characterizes the overall level of inventive activity but also to explore its qualitative characteristics. Integrating quantitative and qualitative methods makes it possible using public information to identify the most active players in the biotechnology market. Such information is of fundamental importance here: a patent establishes a monopoly on individual strands of DNA, genomes, and testing methods, which will be required to realize much future research and many innovations in biotechnology (above all in medicine). In particular,

Transformation of the intellectual property protection system under the influence of the development of biotechnologies

The classical system of level protection of intellectual property, which arose back in the 19th century, excluded the ability to patent the results of scientific and technical activities created using living organisms [*Demaine, Fellmeth,* 2002]. However, the fast-paced development of biotechnologies in the 20th century led to a significant transformation of the system, resulting in the fact that today most countries (including Russia) provide for protection of objects created using biotechnologies.

The system was created in three stages. In the first, which began in the 1930s, inventors gained the ability to patent the genomes and DNA chains of plants. In the second stage, whose beginning is linked with the Diamond vs. Chakrabarty trial [*Ko*, 1992], legal protection was extended to the genomes and DNA sequences of bacteria, animals, and other living organisms, which triggered research into DNA replication. Only relatively recently did scientists gain the ability to patent human DNA sequences, while maintaining the prohibition on patenting the entire human genome or any other anthropomorphic being.

in the United States several hospitals have abandoned researching mucoviscidosis (cystic fibrosis) because the cost of payments to the private company that holds the patent on the gene that determines this disease is too high [*Demaine, Fellmeth*, 2002]. A similar situation occurred with the perinatal test for Down Syndrome because the size of the royalty to the patent holder for the "trisomy 21" gene far surpassed the amount of expected compensation from Medicaid program [*Ibid.*]. Thus, the degree of monopolization of the market and the determination of the main players acquire special importance when analyzing the development trends and prospects of the biotechnology field.

Additionally, analyzing the content of patent documents identifies areas of active technological development and - at least indirectly - makes it possible to assess the quality of the innovations produced using information about the patenting of domestic inventions abroad and the proceedings to transfer the corresponding rights to foreign organizations.

The most significant shortcoming of focusing exclusively on patent information when studying Russia's biotechnology field stems from the quality of available patent information. The public registries of the Federal Service for Intellectual Property (Rospatent)[3] were designed primarily for patent search and identifying technological niches; they are poorly suited to analytical research. The registries can only be searched based on one of three criteria - registration number, publication date, and the International Patent Classification (IPC) code. The information system does not provide the ability to combine them. Search results are presented as a list. Each item is contained in a separate file, so processing the information requires a significant amount of time and effort, including calculating all the quantitative indicators by hand.

Many commercial databases, which aggregate information from the world's major patent offices, provide access to the original patent documents for content-based analysis and - simultaneously - provide the ability to automatically calculate the required indicators. We used one of them, Orbit[4] (formerly "QPat") for our empirical research. The Orbit database enables targeted searching thanks to the ability to combine more than ten search criteria. It also has built-in descriptive statistics tools. However, the filters applied by the system have serious defects as they produce search results with invariably items unrelated to the specified criteria. As a rule, these errors represent at least 40% of the search results, which necessarily affects the quality of the output.

The most reliable source of quantitative data is the World Intellectual Property Organization's (WIPO) database, which contains aggregated data from all national, regional, and international patent offices.[5] However, it lacks access to the actual patent documents and the database itself is updated quite slowly (information about countries' patent activity in 2012 was only added in early 2014).

The need to simultaneously use several sources due to the shortcomings of each has a negative effect on the comparability of the resulting information and calculations. In order to minimize this effect, resources from multiple databases and registries were used simultaneously when sampling and analyzing the information. For an objective assessment of the overall level of patent activity in the biotechnology field in Russia, we relied on data from Rospatent and WIPO resources. Rospatent's public registry of inventions and the Orbit database served as the empirical foundation for content-based analysis targeted at studying more detailed, high-quality attributes.

Besides the problems with the access and the quality of the patent information, another shortcoming of the proposed methodology is that it does not allow other indicators typical of the biotechnology field to be assessed such as attributes related to the personnel, material, technical, and financial resources of biotechnology organizations, production volumes, exports, etc. As mentioned above, because organizations can also use other methods to protect created technologies, the statistical information obtained in the patent database about the volume of intellectual property created will be incomplete. Finally, the ad-

[3] Available at: http://www1.fips.ru, accessed 27.01.2014.

[4] Available at: http://www.orbit.com, accessed 15.01.2014.

[5] Available at: http://ipstatsdb.wipo.org, accessed 07.12.2013.

opted methodology makes international comparisons hard. Nevertheless, we believe that by acknowledging the indicated limitations the selected approach satisfies the goals of our research.

When studying the state of the biotechnology field using patent analysis, the ability to identify patents (and consequently, inventions) related to this area of technology plays a paramount role. The classifications used by the world's major patent offices (EPO, USPTO, JPO) do not have a unified category or class for biotechnologies.[6] Selecting relevant patents requires consulting the *Technology Concordance Table* developed by WIPO for cross-country comparisons.[7] The classification serves as a kind of intermediate key, dividing the IPC classes and groups into areas of technology (the Technology Concordance Table identifies, among others, areas such as "Audiovisual technologies", "Telecommunications", "Microstructural and nanotechnology", etc.)

While aiming to create a unified and generalized classification, technological categories and classes in which biotechnological methods might have taken place were identified. According to the Technology Concordance Table, items registered under the following IPC technology groups belong to "Biotechnology":

- C07G "Compounds of unknown structure"
- C07K «Peptides»
- C12M «Devices for working with enzymes and microorganisms»
- C12N «Microorganisms or enzymes; compositions thereof»
- C12P «Enzymatic or fermentative methods to synthesize chemical compounds or compositions or the separation of a racemic mixture into optical isomers»
- C12Q «Methods of measuring and testing that use enzymes or microorganisms»
- C12R «Encoding scheme for subclasses of C12C-C12Q or C12S, related to microorganisms»
- C12S «Methods using enzymes or microorganisms to isolate, separate, or purify a previously obtained compound or composition».

When submitting an application for a protective document, the applicant may indicate several technology groups (IPC codes) to which the invention being patented belongs. "Biotechnology" overlaps pharmaceuticals considerably (approximately 30%). To avoid any possible bias in the data, the OECD excluded inventions with IPC code A61K "Preparations for medical, dental, or toilet purposes" from this area [*Schmoch*, 2008].

A similar approach was taken in our research but a definite limitation arose because individual subclasses unrelated to biotechnologies are included in these groups (for example, C12P 3/00 "Preparation of elements or inorganic compounds except carbon dioxide"). However, the reliability of the assets is sufficiently high: When screening the objects to analyze which had been selected from the Technology Concordance Table less than 10% of patents were excluded for being irrelevant.

The next step in the research was to perform content analysis of the inventions published by Rospatent in the selected area of technology in 2012 [*Rospatent*, 2013a, 2013b]. The patent activity of Russian applicants abroad was not evaluated, although for each invention included in the research subject an additional search of patent families (protective documents related to the same invention) was conducted at foreign and international patent offices. Therefore our results relate only to the domestic biotechnology market.

In the first stage of the content analysis we conducted a search of patent documents in Rospatent's public registry of inventions based on the following formal criteria: IPC code = C07G-K, C12M-S; patent publication date = 2012; patent publication country = RU (Russia). All patents published in Russia were considered, regardless of the patent holder's status (resident/nonresident) and the document's status (active/expired/expired but renewable/potentially invalid). Then to exclude documents unrelated to the biotechnology field from the resulting body of documents, the selected patents were screened using the following algorithm:

1. Removed patents whose bibliographies indicated IPC code A61K from the list of documents (nearly 20% of the selected documents included codes for both "Biotechnology" and "Medical technology").
2. Searched the «Field of the Invention» section of abstracts using the following keywords: «biotechnologies», «molecular biology», «microbiology», «diagnostic methods», «biochemistry», and others listed in the conceptual part of this paper. If at least one of the keywords appeared in this section of the abstract, then the invention was deemed to relate to «Biotechnology».
3. If the abstract did not indicate the field of the invention, then the «Description» or «Claims» sections were searched for the keywords indicated in the list-based definition of biotechnologies given above (Table 2). Documents for which the search did not detect at least one match with the list of keywords were removed from the set.

The total number of items after the screening was 359. All of the aforementioned steps to select items ensured that the results were representative, thanks to the high level of conformity of the selected documents (the degree to which the examined document possesses the attributes of interest to the researcher i.e. the degree to which the document corresponds to the subject of research).

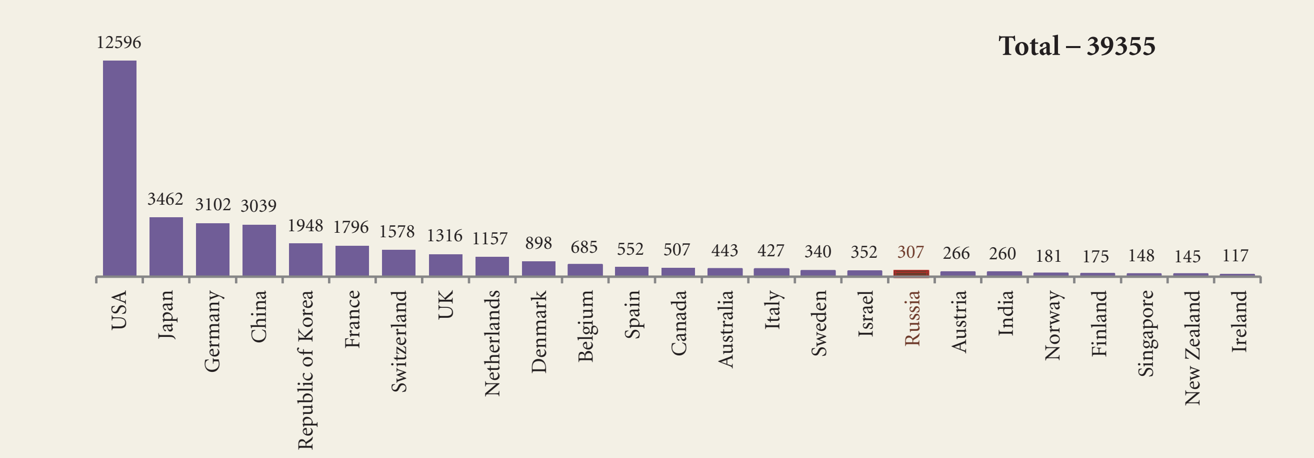
All of the selected documents were assessed using the following criteria during the analysis:

- applicant status (resident/nonresident);
- applicant country (for patents issued to nonresidents);

[6] EPO – European Patent Office. USPTO – United States Patent and Trademark Office. JPO – Japan Patent Office

[7] IPC – Technology Concordance Table. Available at: http://www.wipo.int/ipstats/en/statistics/technology_concordance.html (accessed 01.11.2013).

Figure 1. **Number of patents published for inventions in «Biotechnology» by country of applicants (with more than 100 applicants) for 2012***



*Includes patents granted to applicants in domestically and abroad.

Source: WIPO database.

- applicant type (based on sector membership): state organization, business, institution, non-profit organization, individual;
- IPC codes;
- area of biotechnology (based on the content of the abstract): biomedicine, biopharmaceuticals, bioenergy, industrial, agricultural, forestry, food production, conservation (environmental), biotechnology, aqua-biotechnology;
- field of invention (based on the content of the abstract);
- scope of possible application (based on the content of the abstract);
- existence of patents from foreign patent offices (or filed patent applications);[8]
- for inventions in medicine and pharmacology – which diseases the proposed invention is designed to treat.

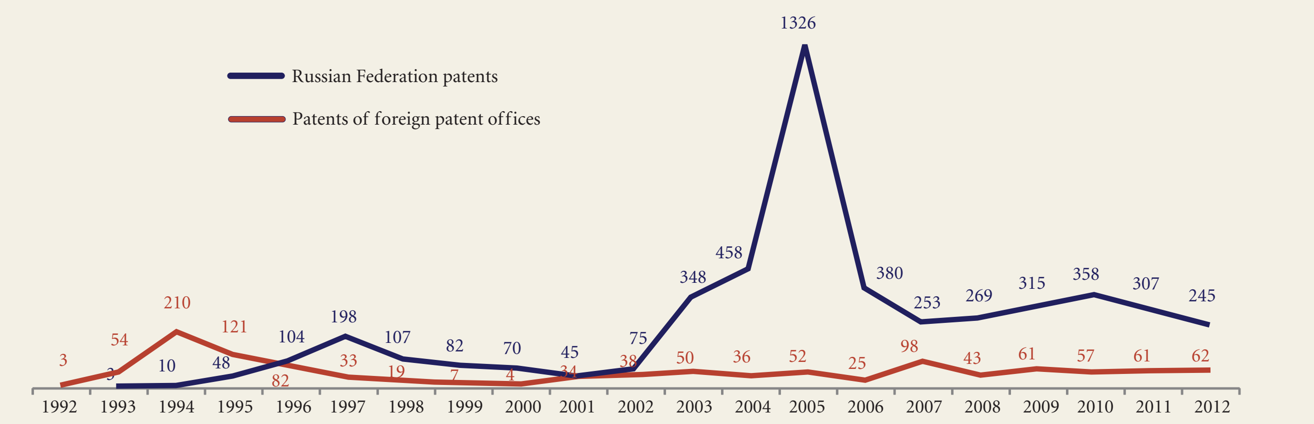
In the next stage the resulting information was encoded and entered into a content-analysis matrix. After the encoding, comprehensive data analysis was performed using the SPSS statistical package. A discussion of the research results is given below.

Russian applicants' patent activity in the biotechnology field

Russia's contribution to global patent activity in the biotechnology field is extremely small. In 2012, out of nearly 40,000 patents published by all the patent offices[9] for inventions in this area, Russian applicants accounted for less than 1%. Russia falls far behind the leading countries, taking 18th place globally for this indicator (Figure 1).

For many years the Russian Federation's documents have dominated the makeup of patents granted to Russian applicants for inventions in "Biotechnology"

Figure 2. **Number of patents for inventions in «Biotechnology» issued to applicants from Russia***



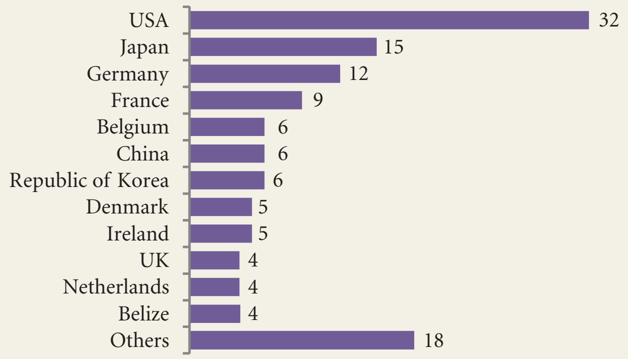
* by patent publication year.

Source: WIPO database.

[8] This was accomplished by searching by number for each patent in the commercial Orbit database. The database supports the ability to obtain information about all patents (and patent applications) related to a single invention and issued at more than 90 patent offices around the world, including the EPO, JPO, USPTO.

[9] When studying the actual level of patent activity, the "number of (filed) patent applications" indicator has traditionally been used. Considering the limitations of available information sources, we have examined here published patents (patent publications). In accordance with the sequence of stages to obtain the protected document and accounting for the average duration of each of them, the assessments presented represent the inventive activity of applicants in the selected area of technology in 2010-2011.

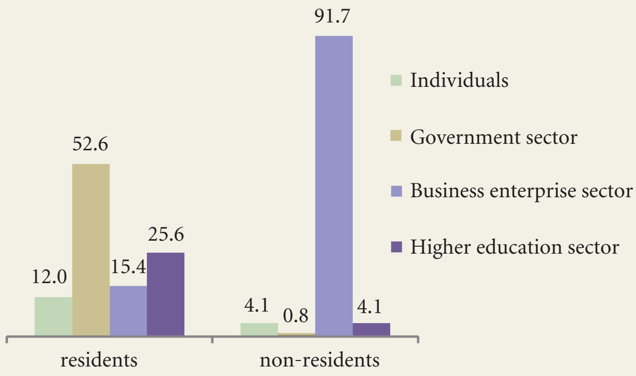
Figure 3. **Number of patents published in the Russian Federation for inventions in «Biotechnology», by applicant country: 2012**



* patents issued to nonresidents.

Source: author's estimates based on Rospatent data.

Figure 4. **Percentage distribution of patents published in the Russian Federation for inventions in «Biotechnology», by applicant type: 2012**



Source: author's estimates based on Rospatent data.

(Figure 2). In the crisis years of the 1990s domestic organizations and inventors actively patented innovations abroad: in 1992-1997 they received nearly as many foreign patents for inventions related to biotechnologies as in the next 15 years (including in countries such as Canada, Germany, Finland, Latvia). Beginning in 1996 we can speak of the realignment of domestic inventors to the internal market: the number of patent applications filed to foreign patent offices shrank, although the circle of countries to which they were submitted expanded slightly. Overall, the level of Russian applicants' patent activity abroad in the biotechnology field remained low over the entire period examined, which may be a result of various factors: the focus on the national technology market as the overriding business strategy; the lack of resources (above all, financial) required to obtain grants at foreign offices; and low competitiveness of domestic inventions.

In contrast to the global situation, internal Russian patent activity in biotechnology over the past twenty years has grown substantially - from 3 patent publications in 1993 to 245 in 2012. However, the relative weight of inventions related to biotechnology in the overall structure of patent publications (1.4%) shows that the area is not a priority for domestic inventors. The fraction of biotechnology inventions have slowly decreased for several years now, and this trend is becoming stable.

Patent assignees

An analysis of the makeup of patent holders testifies to the prominent role that organizations from other countries play in the Russian market for biotechnological innovations. Admittedly, this corresponds with a general trend of growing patent activity in Russia by foreign applicants in other areas of technology as well. Among patents in "Biotechnology" published by Rospatent in 2012, 33.7% are attributable to nonresidents. The remaining two thirds are patents granted to Russian applicants (65.2%). Another 1.1% are documents received jointly by Russian and foreign organizations.

Approximately one quarter of patents for inventions in biotechnology granted to foreign applicants pertain to the United States (Figure 3). Other highly notable countries in this regard are Japan, Germany, and France. For most countries the Russian market is not a priority: out of 121 foreign inventions in the selected set, only 6 were registered exclusively at their applicants' own national patent offices before a patent application was filed in Russia, while the rest already had patents of several (usually more than 10) offices. Furthermore, 91 of the inventions were triadic patent families (they were patented simultaneously at the EPO, JPO, and USPTO). On the whole in 2012, foreign applicants received patents in Russia for inventions that had already been registered at the national level in most cases for more than five years.

According to our calculations, in 2012 patents for inventions related to biotechnologies were issued to 127 domestic and 96 foreign organizations in Russia. The contribution of individuals was relatively small: 9.2% of these patents versus 27.0% of patents across all areas of technology. One can assume that the reason for this is the complexity and high cost of scientific research related to biotechnologies.

As for the assignees of biotechnology patents, businesses are in the lead (42.1%); the relative weight of the government sector is 34.3%. The dominating position of business is the sole result of the makeup of holders of patents granted to foreign organizations, the majority of which are business (Figure 4). In contrast, among resident patent assignees the undisputed leader is the government sector, represented chiefly by the Russian Academy of Sciences, the Russian Academy of Medical Sciences, the Russian Academy of Agricultural Sciences, and state research centres. Among patent assignees for biotechnological inventions issued to Russian applicants, organizations in the government sector accounted for more than half (52.6%), while businesses are patent holders of only

Table 3. **Most active patent-holding organizations in «Biotechnology» (more than three patents)**

Organization name	Number of patents*	Area of biotechnology
State Scientific Research Institute of Genetics and Breeding of Industrial Microorganisms (GosNIIgenetika)	12	industrial biotechnology, biomedicine, biopharmaceuticals
State Research Center of Applied Microbiology and Biotechnologies	9	biomedicine, agricultural biotechnology
Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry of the Russian Academy of Sciences	9	biomedicine, general methods for developing biotechnologies
Gorsky State Agricultural University	6	food production, agricultural biotechnology
ZAO Scientific Research Institute Ajinomoto-Genetika	6	industrial biotechnology
State Scientific Research Center of Virology and Biotechnology 'Vektor'	5	biomedicine
Pasteur Saint Petersburg Scientific Research Institute of Epidemiology and Microbiology	4	biomedicine
Kursky State Medical University	4	agricultural biotechnology
Gabrichevsky Moscow Scientific Research Institute of Epidemiology and Microbiology	4	biomedicine, biopharmaceuticals
OOO SKARABEY	4	agricultural biotechnology

* Includes patents for inventions in "Biotechnology" that were published by Rospatent in 2012.

Source: author's estimates based on Rospatent data.

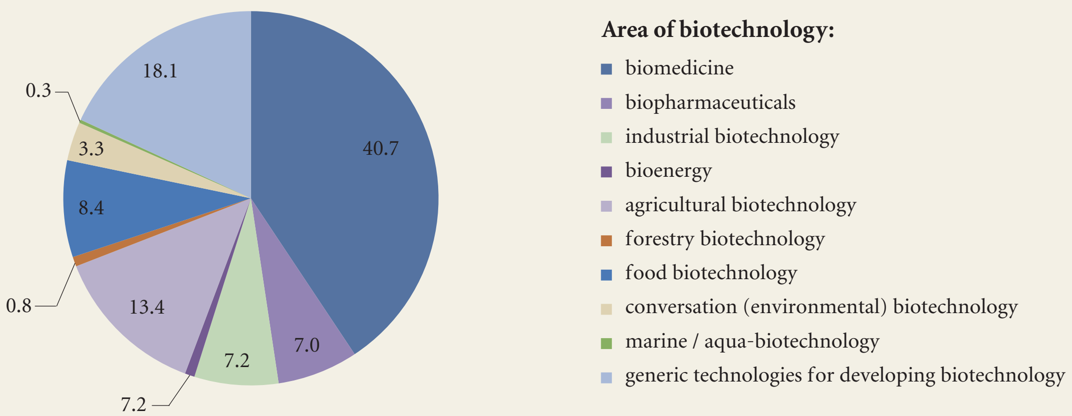
one sixth of protective documents. The level of companies' activity presents the most significant difference in the structure of patenting biotechnological inventions in Russia by residents and nonresidents.

Based on the results of the patent analysis, the most productive Russian organizations on the domestic market for biotechnologies seem to be the State Scientific Research Institute of Genetics and Breeding of Industrial Microorganisms (GosNIIgenetika), the State Research Center of Applied Microbiology and Biotechnologies, and the Institute of Bioorganic Chemistry of the Russian Academy of Sciences (Table 3). These research organizations were the leaders amongst applicants in the IPC class C12 "Biochemistry; beer; alcoholic beverages; wine; vinegar; microbiology; enzymology; mutations; genetic engineering" in the period 1993-2011 [*Rospatent*, 2013a], which makes it possible to treat them as the key agents of biotechnology development in the country. Several universities were in the group of organizations that received several patents in "Biotechnology" in 2012: Gorsky State Agricultural University, Kursky State Medical University, and Kazansky (Privolzhsky) Federal University. The majority of organizations were granted only one patent, most of these were businesses. It is worth noting that, according to the Orbit database, the number of patents granted to the Russian leaders in this field lags considerably behind the world's leading biotechnology companies (for example, Amgen (USA) receives an average of 75 patents annually). However, even these achievements secure a place for them on the list of leading Russian applicants in the biotechnology field.

Areas of inventive activity in the biotechnology field

Analysis of the topical distribution of patents (according to IPC codes), which is traditionally used to

Figure 5. **Percentage distribution of patents published in the Russian Federation for inventions in «Biotechnoogy»: 2012**



Source: author's estimates based on Rospatent data.

study the structure of scientific and technical activities, is not practical in our case because the structure of the set of patents based on IPC class does not give a clear picture of what exactly was invented and patented. For example, three quarters of inventions belong to the IPC group C12N "Microorganisms or enzymes; compositions thereof", which encompasses a significant number of diverse areas and fields of application for the results obtained. On the other hand, studying the distribution of patents by IPC groups and subgroups ("deeper" levels of classification, such as C12N 15/85 "Ti-plasmid" or even C12N 15/861 "Adenoviral vectors") would more likely be of interest to professional biotechnologists by demonstrating detailed subjects and methods for conducting scientific research. As our purposes are different, here we wish to consider the structure of patent activity by analyzing the distribution of inventions based on areas of biotechnology (Figure 5).

As was shown above, biotechnology is a rather heterogeneous field of knowledge which produces results that can be applied in various sectors. Our assessments indicate that inventions related to biomedicine are currently being patented particularly intensively in Russia. Moreover, these technologies hold a leading position in the makeup of patents granted to both resident (44.0%) and foreign (35.5%) applicants. Furthermore, 7.0% of the patents in the selected set were related to biopharmaceuticals.

Judging by the indicators of patent activity with regard to technological priorities in health care, the most numerous group consists of inventions related to the diagnosis and treatment of infectious diseases, including widespread illnesses - tuberculosis, pseudotuberculosis, viral diseases (above all, influenza and hepatitis A and B) - and illnesses that are encountered less commonly in developed countries today (melioidosis, plague). 48 inventions in the selected set targeted treatments for these illnesses. Such attention in Russia to a multitude of diseases that have long been known is primarily the result of a consistently large number of reported cases of these diseases. For example, according to the World Health Organization, in 2010 in Russia there were 120,000 reported cases of tuberculosis [WHO, 2013].

21 patents in biomedicine and biopharmaceuticals (one seventh of the total), were granted for inventions concerning methods to diagnose and treat oncological diseases, including methods designed for specific cancers (breast, stomach, and bladder cancers) as well as general methods for treating malignant tumours. Considerable attention is also being given to the development of methods for preventing and treating diseases of the circulatory and cardiovascular systems (8 and 7 patents, respectively) although it should be noted that in this case the level of inventive activity falls far short of what the problem's importance should merit: these very diseases are the main cause of death from non-infectious diseases both in Russia and around the world [WHO, 2013].

Other less represented groups in the selected set include methods for treating diseases of the endocrine (diabetes) and immune systems (production of immunoglobulins and immunomodulators); illnesses caused by genetic mutations (cystic fibrosis, Huntington's disease); skin lesions, musculoskeletal system, and the reproductive system. Several inventions relate to preventing the development of diseases during pregnancy and the neonatal period. A small number of inventions (3 patents) concern general methods for raising the effectiveness of diagnostic methods.

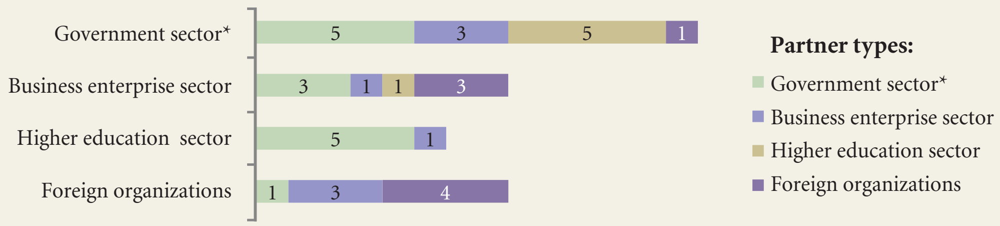
The second largest group in the selected set consists of inventions that may be considered universal methods and technologies applicable in a broad range of fields and generally used to develop biotechnologies. This group, which encompasses 65 patents, relates to methods for DNA sequencing, recombinant DNA technology, the culturing of cells, issues, and microorganisms, and genome analysis. Such inventions are patented to a larger degree by nonresidents: 28.9% of their inventions are in these technologies (for Russian applicants, they account for 12.8%). This distribution, especially if it becomes a consistent trend, may negatively affect the future development of domestic biotechnologies: monopolization of technologies by foreign assignees limits opportunities for their practical application by domestic inventors and manufacturers.

Patents in agricultural biotechnology, which form the third largest group, on the contrary, were granted in most cases (74.5%) to Russian applicants, who developed and patented methods for diagnosing livestock diseases, ways to protect plants from diseases, and new types of fertilizers. Plant cell sequencing and breeding transgenic varieties of plants with specific traits (larger yield, controlled height, etc.) are not areas of active development in Russia: in the selected set such inventions account for only 7 patents, and all of them belong to foreign organizations.

Roughly 7% of patents were granted for inventions in industrial biotechnology. These patents include new ways to get and produce microbial metabolites (above all, amino acid), chemical substances obtained from renewable sources of raw materials (particularly, n-Butanol, which is used in many industrial fields from the paint and varnish industry to the medical industry), enzymes (amylases, lipases, etc.), and new biomaterials. In this case, the definitive leader is the State Scientific Research Institute of Genetics and Breeding of Industrial Microorganisms: it owns one quarter of all patents issued in 2012 in this group.

Inventions in more rare and specialized areas of biotechnology (bioenergy, forestry, environmental, and marine biotechnology) are patented extremely rarely. Their share of the overall markup of patents published in the biotechnology field in 2012 was not more than 5%. Only three inventions were patented in the bioenergy field in 2012 for new types of biofuels. Moreover, they all belong to foreign applicants. Russian organizations dominate among patent assignees for inventions in environmental biotechnology. Inventions patented in this area involve methods to clean waste water, air and industrial waste, and the

Figure 6. **Number of joint patents published in the Russian Federation for inventions in "Biotechnology", by applicant type: 2012**



* Including executive agencies acting as the patent holder on behalf of the Russian Federation.

Source: author's estimates based on Rospatent data.

interior of trunk pipelines used to transport natural gas and oil products.

Cooperation in the biotechnology field

The level of cooperation in the biotechnology field may be measured by the number of joint patents held by several organizations or individuals. 40 items in our selected set fit into this category, four of which are patents received jointly by Russian and foreign organizations, and the same number are joint patents held by several foreign organizations (Figure 6).

In 13 patents the Russian Federation was one of the indicated assignees, as represented by various ministries and agencies. These joint patents should certainly not be viewed as an indication of cooperative relations; they are more likely an indication of the distribution of state and municipal contracts to perform work in the biotechnology field for state or municipal needs. As stipulated in the Civil Code of the Russian Federation (art. 1373), as part of such contracts the ordering party may receive the exclusive right to the created results, which means becoming the patent assignee, either solely or jointly with the organization that fulfilled the contract. All such patents in the selected set relate to biomedicine and provide legal protection for strains of cells, and methods for diagnosing and treating various diseases.

According to our calculations, organizations in the government sector are more frequently involved than others in joint projects in the biotechnology field: five patents were issued for inventions created jointly by several state organizations and the same number belong simultaneously to organizations in the government sector and Russian universities, which are far rarer but have nevertheless been involved in joint research and development. The business enterprise sector also has a small number of joint patents in the biotechnology field (Figure 6).

Several patents belong simultaneously to Russian and foreign inventors; nearly all of them are joint patents of an organization registered in Japan with a subsidiary that is a resident of Russia. Therefore, we may conclude that domestic scientific, educational, and industrial organizations are virtually uninvolved in joint projects with foreign partners in the biotechnology field, which is most likely a negative factor in the development of this area of technology in the country. International cooperation is a necessary condition for technological progress. It encourages the exchange of information and professional experience, which is especially important for the advancement of biotechnologies in Russia, which lags behind many countries in terms of the number of biotechnology organizations, the scale of research activities, and the volume of biotechnology products produced and exported. Factors stifling international cooperation include tax and customs policies, financial reporting procedures, and execution of monetary transactions [NRC, 2013].

Conclusion

One of the current priorities for the modernization of the Russian economy is to take a leading position in the development of biotechnologies and increase the production and consumption of biotechnological products. Biotechnologies as a field of knowledge were developed during the Soviet period [*Rabinovich*, 2007]. However the active phase of state incentives for their development began relatively recently with the adoption of a national program entitled "Development of Biotechnologies in Russia in 2006-2015". Nonetheless, technologies related to living systems have been one of the strategic areas for the development of science and technology since 1996. Despite this fact, Russia's share of the global market for biotechnologies is less than 0.1% [*BIO 2020*, 2012].

The results of our patent analysis presented here are evidence that Russia has not yet accumulated a critical mass of inventions that will subsequently serve as a resource for the active development of the biotechnology field. Despite the fact that the makeup of patents related to "Biotechnology" is dominated by patents granted to residents, the share of foreign organizations' inventions is quite high – indicating that the Russian market for biotechnology remains dependent on foreign technologies. Considering that non-residents are actively patenting general methods and techniques for working with biomaterials in Russia, which makes it possible to "close" certain fields and areas of scientific research, this trend may not only be perpetuated but also intensified in the future.

Among Russian organizations, government sector scientific organizations have demonstrated the most activity in patenting inventions related to biotechnology. At present they may be considered the primary driving force behind the development of biotechnologies in the country. Companies patent the results of research and development in this area of technology less often than other types of organizations. This distribution of roles may become a serious barrier to introducing inventions to production because the majority of applicants in the government sector are organizations that largely lack productive infrastructure.

Patent analysis has made it possible to identify specific trends that may negatively impact the future development of biotechnologies in Russia. The dependence on foreign technologies, the business enterprise sector's low level of inventive activity, the lack of serious cooperative relations, the inadequate level of development in such relevant areas of biotechnology as bioenergy, environmental and marine biotechnologies - all these problems require more in-depth investigation and the preparation of a well-grounded and effective approach to solving them. F

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