

DISTRIBUTION OF TECHNOLOGICAL COMPETENCIES IN THE FIELD OF THE ANTIDIABETIC DRUGS DEVELOPMENT IN THE REGIONS OF THE RUSSIAN FEDERATION ¹

The high level of uncertainty in the Russian pharmaceutical competitive environment creates a necessity of using open data that indicate the degree of the organizations' technological competencies. The Analysis of the information on the organizations' localization in the regions allows generating a regional competence profile, which can be used to plan the drugs' production. The study aims to analyse the distribution of technological competencies in the Russian regions by assessing the prospects for locating production sites of foreign and Russian organizations specialising in the antidiabetic drugs development. We hypothesise that the analysis of the distribution of technological competencies in the regions reduces the market's uncertainty for deciding on the localization of the socially significant industries. The research model is based on the methods of average-weighted, ranking and categorical analysis of the patent and registration data for shaping the regional competence profiles. The implementation of this method of analysing the organizations' technological competencies is showed on the example of 18 regions that have production sites of antidiabetic drugs. We substantiated the allocation of 5 types of regional profiles, characterised by similar opportunities and threats for new participants in the pharmaceutical market. We revealed that the model of the cooperation behaviour should consider the technological profile at the regional level. At the same time, the model of competitive behaviour to a much lesser extent depends on the regional characteristics of localized production. The methods of constructing the region's patent and product ratings and their categorization (with allocation of typical behaviour models) allow determining the technological opportunities for increasing the availability and quality of the Russian pharmaceutical products. Moreover, such methods allow identifying the prospects for long-term cooperation with technological leaders at the regional and industrial levels. That is especially important for implementing the concept of the national drug safety and increasing the availability of the socially significant drugs.

Keywords: Russian pharmaceutical market, technological competence, regional competence profile, patent analytics

Introduction

Nowadays, pharmacy is one of the most dynamically developing and highly competitive technological areas. According to the estimates made by Deloitte analytical agency, the overall drugs production in Russia increased by 3.2 % in 2017 amounting to 295 billion roubles, import growth rate (+21.6 % in monetary terms) exceeded export growth rate (+14.6 %), while imports exceeded exports by almost 15 times². By the end of 2018, the Russian pharmaceutical exports (excluding supplies to the countries of the Eurasian Economic Union (EAEU)) amounted to 26.1 billion roubles, which is 19.3 % higher than that in the preceding year³. Notably, in November 2018 antidiabetic drug exports showed the largest share in the overall structure of drug exports from Russia (24.78 %), mainly due to sales of the Sanofi's Lantus® SoloStar®⁴. At the same time, the drugs for diabetes treatment reached the 14th

¹ © Kortov S. V., Shulgin D. B., Rodnin A. V., Karimova A. A. Text. 2019.

² Strategiya tsifrovizatsii kak sposob organizatsii vzaimodeystviya s konechnymi potrebitelyami. Tendentsii farmatsevticheskogo rynka Rossii — 2018 [Digitalization strategy as a way of organizing interaction with end users. Russian Pharmaceutical Market Trends — 2018]. (2018). Moscow: Deloitte. Retrieved from: <https://www2.deloitte.com/content/dam/Deloitte/ru/Documents/life-sciences-health-care/russian/russian-pharmaceutical-market-trends-2018.pdf> (Date of access: 25.01.2019).

³ RNC Pharma: the export of drugs from Russia showed a record high ruble dynamic in 2018 [RNC Pharma: v 2018 g. eksport lekarstv iz Rossii pokazal rekordno vysokuyu rublevuyu dinamiku]. (2019). Farmatsevticheskiy vestnik [Pharmaceutical Bulletin], 9(964). Retrieved from: <https://pharmvestnik.ru/content/news/RNC-Pharma-v-2018-g-eksport-lekarstv-iz-Rossii-pokazal-rekordno-vysokuu-rublevuu-dinamiku.html> (Date of access: 23.03.2019).

⁴ Eksport GLS iz Rossii po itogam noyabrya 2018 goda. Po dannym IAS «Klifar: Import-Eksport» [FPPs export from Russia in November 2018, according to CliPhar data]. (30.08.2019). Remedium. Retrieved from: http://www.remedium.ru/state/Eksport_GLS_iz_Rossii_po_itogam_noyabrya_2018_goda/ (Date of access: 20.09.2019).

position in the rating of pharmacotherapeutic groups ranked by the imports, providing a 2.29 % share in the overall drugs imports to Russia in this period⁵.

A distinctive feature of the pharmaceutical industry is the high importance of scientific research in the process of obtaining a novel product, on which strict requirements are imposed by both market regulators and consumers themselves [1–3]. The strategic tasks for economic and social development in the Russian Federation are descended to the regions, determining the industry-specific development vector. In turn, implementation of the state tasks on the level of industry significantly increases the economic, innovative and technological capacity of the region. Solving the problems of providing the population with the socially important products, particularly, antidiabetic drugs, manufacturers are forced to constantly search for the new technological opportunities to improve the availability and quality of their products while taking into account the regional industry's capabilities. While assessing the prospects for locating production sites of foreign and Russian organizations specialising in the antidiabetic drugs development, it is advisable to study the distribution of technological competencies in the regions. That method is applied in practice infrequently due to the lack of necessary information or standardized approaches to the analysis.

For determining the specific tasks of the product and technological development, manufacturers need the comprehensive data on the current state of the market they introduce their products to and, in particular, on the region where the production site is planned to be located. Such knowledge may include the observed behaviour patterns of the competing entrepreneurs and the current level of their innovative and technological development (including their specific technological competencies) [4], possible forecasts on the reproduced drugs placed on the market [5].

Obviously, for all the pharmaceutical market participants, any information that could identify their future intentions is of a commercial nature, thus, most often such information is hidden from an external observer. For this reason, the pharmaceutical market is characterized by a high level of uncertainty of the competitive situations, which might complicate the adoption of the strategic decisions affecting the enterprise product and technological development in regions with different levels of technological competencies [6]. The confidentiality of the information of a commercial nature seriously complicates the generation of new knowledge on the competitors' behaviour. It enables development of analytical models based on open data characterizing the competency profiles of the regions in which the production capacities of drug developing organizations acting in a particular therapeutic field are located.

At the same time, some information is publicly available, the analysis and generalization of which might allow to solve the problem of market uncertainty to some extent. Such data may include, in particular, patent data, as well as registration data of official drugs stored in the state drug register. There are indications that a comprehensive analysis of these data enables the assessment of the technological competencies of the key market players in regional pharmaceutical clusters.

The study aims to analyse the distribution of technological competencies in the Russian regions based on open sources of information from the perspective of assessing the prospects for locating production sites of foreign and Russian organizations specialising in the production of antidiabetic drugs.

The objects of the study are the antidiabetic product portfolios of the drug development organizations currently localized in the Russian regions. Patent and non-patent characteristics of the considered objects were used to analyse technological profiles of the region.

Approaches to the analysis of innovative and technological competencies at the levels of the industry, enterprise and region

For Russian pharmaceutical enterprises, the main industry document defining their corporate technological strategy (corporate strategy for the development of the technological competencies) is the federal target program "Development of the pharmaceutical and medical industry of the Russian Federation for the period up to 2020 and beyond"⁶. The Ministry of Industry and Trade also submitted

⁵ Import GLS v Rossiyu po itogam noyabrya 2018 goda. Po dannym IAS «Klifar: Import-Eksport» [FPPs import in Russia in November 2018, according to CliPhar data]. (30.08.2019). Remedium. Retrieved from: http://www.remedium.ru/state/Import_GLS_v_Rossiyu_po_itogam_noyabrya_2018_goda/ (Date of access: 20.09.2019).

⁶ O vnesenii izmeneniy v gosudarstvennyuyu programmuy Rossiyskoy Federatsii "Razvitie farmatsevticheskoy i meditsinskoy promyshlennosti" na 2013–2020 gody. Postanovlenie Pravitelstva Rossiyskoy Federatsii ot 28.12.2017 № 1673. [On amendments to the state

for discussion a draft of the Strategy for the Development of the Pharmaceutical Industry of the Russian Federation for the period up to 2030⁷. One of the key tasks of the aforementioned Strategy was to create the export potential of the pharmaceutical industry by introducing modern technological competencies and launching competitive innovative drugs to the market.

According to the Remedium group⁸, the import substitution process continues in order to provide the national drug safety of the Russian Federation. One of the trends in the pharmaceutical market in 2018 was the increment in the share of domestic drugs for diabetes treatment. Domestic drugs provided more than 50 % of the sales in the segment of antidiabetic drugs in physical terms and about 21 % in value terms. The innovative technological competencies of pharmaceutical organizations in the field of developing antidiabetic drugs and launching them in the market determine the direction for choosing the corporate technological strategy of the organizations specialising in the production of these products.

In order to make informed decisions in the field of innovative and technological development, organizations must take into account both the external competitive environment and their own core competencies. The basic tools of competitive analysis, used for the examining technological competencies at the industry and regional levels, usually identify the external factors associated with the activities of competitors in a similar technological field. The benchmarking technologies enable the study of the best practices and implementation of the organizational strategic tasks not only in a similar technological field, but also in related fields. Moreover, such technologies demonstrate the applicability of this experience to development of a company's own key competencies [7]. Benchmarking of pharmaceutical organizations can reduce potential risks in strategic miscalculations in the face of uncertainty [8]. In this regard, it is necessary to use these tools when determining and adjusting the technological strategy of an organization, focusing not only on the effective practices of competitors, but also on their applicability to the existing set of innovative and technological competencies of organizations localized in a particular region.

In order to increase the validity of the strategic decisions and reduce investment risks associated with them, a wide range of technological forecasting tools is used [9]. These tools possess the varying degrees of objectivity. Studies conducted on the basis of patent data are less subjective. Drawing on them, a fairly wide list of scientific and technical indicators of innovative activity can be obtained. To some extent, such indicators would correlate with market parameters that are an organization's trade secret.

Practical experience shows that the main obstacle that pharmaceutical organizations have to deal with while analysing innovative and technological competencies of competing organizations, that were shaped in accordance with either a region's characteristics or an industry's development level and the market's needs, is the difficulty in interpreting the existing non-commercial data while lacking commercial data. In these conditions, for proving validity of prognostic models it is important to use an approach that includes certain non-commercial data, in particular, patent and registration data on drugs, being the specialization of the drug developing organization.

The knowledge on the patent portfolios of the organizations allows to draw informed conclusions about the level of innovative and technological competencies at any of the considered levels: corporate, regional or industry. This knowledge is especially important for the analysis of innovative and technological competencies of organizations such as developers of original and reproduced drugs, since they significantly improve the predictive accuracy of an analysis of technological landscape [5]. The patent data is not widely used to analyse technological competencies, despite the fact that studying the optimal quantitative and qualitative composition of patent portfolios and patenting strategies of organizations specializing in the drug development allows to make more informed strategic decisions at the corporate or industry level [6].

program of the Russian Federation "Development of the pharmaceutical and medical industry" for 2013–2020. Decree of the Government of the Russian Federation dated December 28, 2017 No. 1673]. Retrieved from: <http://docs.cntd.ru/document/556185067> (Date of access 01.04.2019).

⁷ Strategiya razvitiya farmatsevticheskoy promyshlennosti Rossiyskoy Federatsii na period do 2030 goda. Proekt dokumenta [Strategy for the Development of the Pharmaceutical Industry of the Russian Federation for the period up to 2030. A draft]. Retrieved from: <http://gasu.gov.ru/stratpassport> (Date of access 15.03.2019).

⁸ Rossiyskiy rynek protivodiabeticheskikh LS demonstriruet aktivnyy rost [The Russian market of antidiabetic drugs shows active growth]. (2019). Remedium. Retrieved from: <http://www.remedium.ru/news/rossiyskiy-rynok-protivodiabeticheskikh-ls-demonstr/> (Date of access: 10.02.2019).

Interpreted patent and registration indicators of R&D activity associated with the pharmaceutical organizations shaping a regional competency profile

Indicators	Interpretation	Applicability
<i>Patent indicators of an organization</i>		
Overall number of patents owned by an organization in the technological field, including the number of valid patents	Patent activity of an organization	Identification of R&D competencies of an organization or a region
Average patent lifetime of an organization	Commercial success of products	Current experience of an organization and its success
Technological and product specialization (patents share of a selected therapeutic area)	Product and technological specialization of an organization	Performance experience of an organization in the chosen direction
Co-owned patents	Presence of scientific and technical cooperation availability	Choice of partners
<i>Registration data on the products manufactured by an organization</i>		
Number of International Nonproprietary Names (INN) of the drugs	Product specialization of an organization	Specialization experience of an organization in the chosen direction
Pharmacotherapeutic groups of drugs	Level of efficiency, safety and product quality	Potential demand for the products
Number of trade names, their relation to the number of INN drugs	The breadth of product range (number of drug modifications)	Current experience of an organization and its success
Data on the regional localization of the drug production stages	Presence of scientific and technical cooperation	Choice of partners

The methods of constructing patent and technological landscapes are actively used to solve a wide range of scientific, practical and business problems of the industrial enterprises [10, 11]. They include identification of promising novel products and technologies that are developing worldwide [12, 13], assessment of possibilities of scientific and technical cooperation [14], development of a decision support system based on predictive models and competitive analysis [6] and innovative scouting [15], as well as planning of an overall enterprise development strategy [16]. A number of foreign authors wrote about the possibilities of using patent data for creating technological roadmaps [17], identifying semantic relationships in related technological fields, and analysing promising markets [18, 19]. However, despite a significant number of foreign publications, Russian pharmaceutical companies that manufacture the drugs do not pay due attention to these tools and do not consider the possibility of using them in the regional aspect.

An important source of information on the competitive environment in the pharmaceutical market is the drugs registration data stored in the state drug register⁹. However, these data characterize only product specialization. Thus, it is necessary to conduct joint analysis of registration and patent data and subsequently interpret it. Based on both the listed sources and our own developments, we have compiled a complete list of patent and registration indicators (Table 1). They must be analysed together for a correct economic interpretation of the actual presence of competencies in the field of development and market launch (R&D competencies) of drugs both at the level of a specific organization, and at the level of regions of their localization.

Some patent and non-patent data on the drugs and organizations that manufacture them can be interpreted and applied in a similar way for building prognostic models that examine cooperative behaviour of organizations localized in a particular region. This circumstance makes it appropriate to conduct a joint analysis of patent and product characteristics of these organizations, shaping a competency profile of a region in which they are localized. Due to the analysis of these characteristics in an integrated model, the regions get assigned the rank and categorical characteristics. Such characteristics demonstrate the level of technological competencies and indicate the priority model of cooperative or competitive behaviour of the main pharmaceutical market players both at the regional and industry levels, based on open data administered by the federal executive authorities.

⁹ Gosudarstvennyy reestr lekarstvennykh sredstv [State drug register]. Retrieved from: <http://docs.cntd.ru/document/1200123389>, <http://grls.rosminzdrav.ru/grls.aspx> (Date of access: 06.03.2019).

Research methodology

Regions and organizations. The test sample includes 108 production sites of 65 manufacturing organizations (among them 28 are Russian) that have product portfolios containing antidiabetic drugs produced on the territory of the Russian Federation.

All the organizations that have antidiabetic drugs in their product portfolio were divided into classes and subclasses according to the economic and geographical criterion depending on localization of their production sites.

Class I: organizations of foreign origin that currently do not have localized production in any region of the Russian Federation, but have patented and / or non-patented drugs (including those that have been excluded from patent protection) that are approved for use on the territory of the Russian Federation (foreign organizations such as exporters of imitation and / or innovative products belong to subclasses Ia and Ib, respectively). 25 organizations (38.4 %) are assigned to Class I.

Class II: organizations of foreign origin that partially localized the production of generic drugs (foreign imitating organizations are included in subclass IIa) and / or original drugs under the license in the Russian Federation (foreign innovative organizations belong to subclass IIb). 12 organizations are assigned to Class II (18,5 %); they are localized in seven regions of the Russian Federation.

Class III: domestic organizations that implement the state tasks of import substitution (domestic imitating organizations compose subclass IIIa) and / or pursue an export-oriented strategy (domestic innovative organizations belong to subclass IIIb). 28 organizations (43.1 %) localized on the territories of 15 regions of the Russian Federation are assigned to Class III.

Classes II and III determine the level of technological competencies of the region in which their production sites are localized. We selected a test sample that includes 18 regions where the corresponding production sites are located.

Research Model. Technological competencies in the field of developing antidiabetic drugs and launching them in the market were assessed in accordance with the data characterizing patent and product indicators of activity of organizations localized in the regions of the Russian Federation. Since only organizations specializing in the selected therapeutic field that have registration certificates for the release of the antidiabetic drugs were included in the test sample, their products were examined for the presence or absence of legal protection in the form of granted patents. What is more, we identified and analysed patents for technological improvements related to patented antidiabetic agents and generics. Providing that a foreign organization has valid patents for products manufactured in production sites in several regions, the degree of production localization was analysed. Competencies in the field of innovative product development in those regions that have full-cycle production were rated higher compared to the enterprises with individual technological stages (packaging, producing quality control).

An analysis of the regional technological competencies was based on the average-weighted values of patent and registration data on antidiabetic drugs produced at production sites of the sampled organizations. An analysis of patent and registration data (patent and product portfolios of the organizations) was conducted on a case by case basis for each organization considering regional production localization.

In order to standardize the approach to the analysis of technological competencies at the regional level, we used the method of ranking and categorizing the regions in accordance with a set of patent and registration indicators.

When processing the data, both graphic and factor approaches were used to analyse product and operational factors traditionally used to assess the competitiveness of organizations and select promising models of their technological development [20].

Step by step, we ranked organizations assigning categories on the basis of multivariate ABCD analysis. In the classical model of the ABCD analysis of goods and their producers, category boundaries are determined by empirical ratios of the total cumulative shares that each category contributes to the observed indicator [21, 22]. In connection with the specifics of the data distribution, we considered it appropriate to use a mathematically corrected ratio of categories, taking into account the relatively uniform severity of the characteristic in a proportion of 50:30:20:0.

Since the level of technological competencies in organizations specializing in the manufacturing of innovative products is much higher than in organizations that produce imitation products, it is advisable to build two ratings of the regions: for both patent and product portfolios.

The use of the aforementioned methods allows to reduce the uncertainty of the regional competitive environment and make a more informed strategic decision shaping an organization's product and technological development [23, 24]. There is a positive experience in using the individual elements of our proposed methodological approach for making strategic decisions in the field of pharmaceutical production development [25, 26].

The hypothesis of the research was to test whether it is possible to apply the distribution analysis of the technological competencies in the regions of the Russian Federation in order to reduce the market environment uncertainty and objectify decisions made by commercial organizations about the prospects of localizing socially significant industries in a particular region.

The following data sources were used for the purposes of the present study:

- State Drug Register;
- alphabetical subject index to the International Patent Classification of the current edition (IPC-2018.01)¹⁰;
- database of the Russian patented inventions (RUPAT) maintained by the Federal Institute of Industrial Property (FIPS)¹¹;
- collections of the publication server maintained by the European Patent Office (Espacenet Patent Search)¹².

In order to create a study database, we identified competing organizations specializing in bringing similar products to the Russian pharmaceutical market. Based on the test sample of 65 organizations participating in the study, a combined search was conducted for information about their products and patents available. A patent search included a search for the organizations names, taking into account the presence of a sign of assigning a patent to one or more sections of the international patent classification (IPC):

- A61K38/28 (drugs having peptides. Insulins);
- A61P3/10 (hyperglycaemia treatment drugs);
- A61P5/50 (drugs for increasing or potentiating the activity of insulin);
- C12N15/17 (DNA or RNA fragments encoding insulin synthesis);
- C07K14/62 (peptides containing more than 20 amino acids, insulins).

Based on the search results, we created an extensive body of documents that included 267 patents. According to the State Drug Register, as of March 1, 2019, 682 drugs registration certificates used for diabetes treatment were registered in the manner prescribed by law, of which 502 were valid. The compliance of the medicinal product authorized for use in Russia and the corresponding patent was established using a method of continuous viewing of the patent abstracts, descriptions and claims. When analysing a list of 38 basic indicators of organizations' scientific and technological activity, 9 of the most significant innovative and technological indicators characterizing the patent and product portfolios of organizations were selected for the purposes of the present study. Based on the results of the content analysis of patent and registration databases on pharmaceuticals, organizations were ranked and categorized (with assigning to the organizations the corresponding ranks and / or categories of product and innovation and technological development). The summation of these characteristics within the regional production clusters made it possible to assess the existing production resources of the regions and R&D competencies.

Ranking and categorization of the regions based on the analysis of patent and registration data on manufactured products

The use of tools of patent analytics made it possible to get a sense of the organizations' behavioural model and their technological development directions within the political tasks concerned with the drug supply and national drug safety improvement, which were set by the Government of the Russian Federation to the regions and the pharmaceutical industry as a whole. Combining the results of the

¹⁰ Mezhdunarodnaya patentnaya klassifikatsiya [International Patent Classification]. Retrieved from: <https://www1.fips.ru/publication-web/classification/mpk?view=list&edition=2018> (Date of access: 01.03.2019).

¹¹ Federalnyy institut promyshlennoy sobstvennosti. Informatsionno-poiskovaya sistema [Federal Institute of Industrial Property]. Retrieved from: <http://www1.fips.ru/iiss/search.xhtml> (Date of access: 10.03.2019).

¹² Sistema poiska patentnyy dannyykh Espacenet [Espacenet Patent Search]. Retrieved from: <https://worldwide.espacenet.com> (Date of access: 01.03.2019).

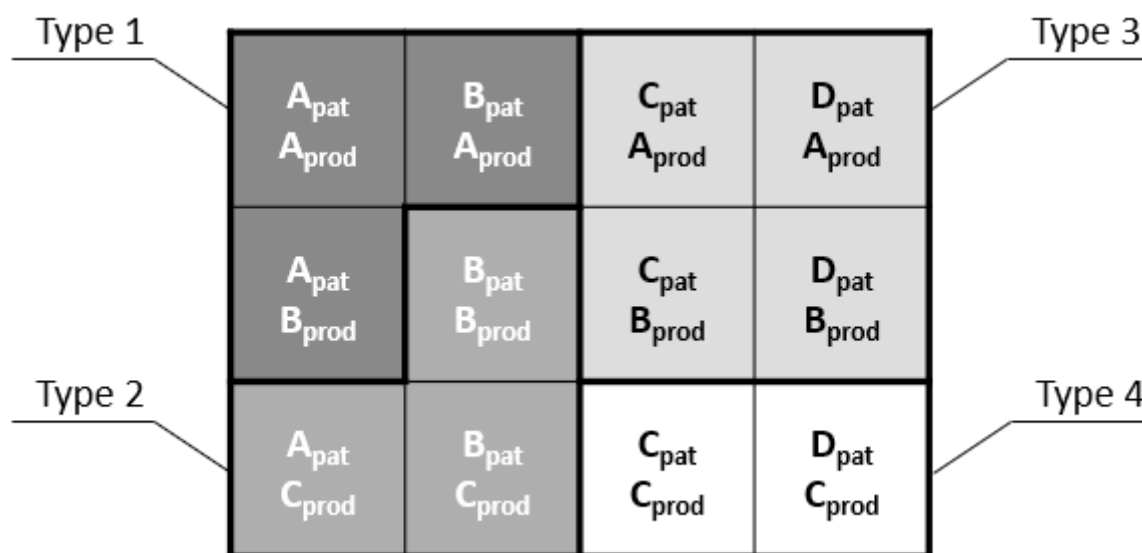


Fig. Region types depending on the competencies level

regions ranking allowed us to form 12 categorical combinations (shown in FIG.) that most fully reflect the region's technological competency profile.

The patent rating is built by a three-level ranking of the regions according to the number of patented developments in the analysed therapeutic field, the share of valid patents for the developed products and the average life time of these patents. The first 11.1 % of the regions that hold the highest positions in the patent rating are classified as A_{pat} , the next 11.1 % of the regions are categorized as B_{pat} , and 22.2 % are included in the C_{pat} category; 55.6 % of regions in which the production of innovative antidiabetic drugs is not localized are grouped in the D_{pat} category.

The product rating is built similarly to the patent rating. As ranking indicators we used the number of nomenclature units of products manufactured at the regional production facilities under international non-proprietary names and under specific trade names, taking into account the differentiated forms of release and dosages indicated in registration certificates, as well as the relative share of innovative developments in the region's product profile. The first 16.7 % of the regions that occupy the highest positions in the product rating are categorized as A_{prod} , the next 33.3 % of the regions are categorized as B_{prod} , the remaining 50.0 % are included in the C_{prod} category, while regions in which the production of antidiabetic drugs is not localized are grouped in the D_{prod} category and not included in the sample.

Since a number of combinations is characterized by a similar interpretation of the level of technological competencies, further we are going to use 5 larger types of regional competency profiles, which are characterized by similar opportunities and threats for new players, and therefore determine the models of their cooperative behaviour.

Type 1 includes the regions with a high level of competencies for the antidiabetic drugs development and market launching with a predominance of innovative products in the product portfolio (A_{pat} , A_{prod} , B_{pat} , A_{prod} , A_{pat} , B_{prod}), which we defined as regions — “successful innovators” with developed technological competencies which they have been successfully implementing for quite some time. Upon entering this type of region, small imitating companies (previously identified subclasses of organizations Ia and IIIa) will be absorbed by large players. New large players will build strategic alliances with joint development of complementary goods (a priority for large innovative organizations of subclasses IIb, IIIb with experience in project management in the Russian market, and, to a lesser extent, for organizations of subclass Ib). The level of competition is too high for the production of similar goods (substitute products) in such regions, qualified personnel may switch to work in more successful companies, which would affect the product quality.

Type 2 consists of the regions with high innovative potential, but insufficient experience in product development and launching, or regions which have enterprises with poorly diversified product portfolios (B_{pat} , B_{prod} , A_{pat} , C_{prod} , B_{pat} , C_{prod}), which we defined as regions — “young innovators”. They can be used as a platform for localization of the innovative productions of foreign origin which are new to the Russian market (a subclass of organizations Ib), previously supplied to the Russian Federation from foreign exporting sites. Organization of weakly diversified lines of production on the patent license is

a priority, as well as cooperation with the same young Russian innovators (subclass IIIb) as a part of a regional cluster development program, attraction of subsidies for the development of the region's export potential, cooperation with universities aimed to strengthen innovation potential.

Type 3 encompasses the regions with a high level of competencies in the production and marketing of antidiabetic drugs with a predominance of imitation products in the product portfolio (C_{pat} , A_{prod} , C_{pat} , B_{prod} , D_{pat} , A_{prod} , D_{pat} , B_{prod}), or regions – “successful imitators”, in which a large number of generic antidiabetic drugs is available. There is practically no R&D experience, only some technological improvements in the production process are possible. In these regions, it is advisable to place production for generic companies (subclass Ia, mainly localized in Eastern Europe and the BRICS countries), if their production is not costly, or to produce commercially successful products of foreign organizations that already have localization experience in the Russian Federation (subclass IIa).

Type 4 combines the regions with a low level of technological competencies and little experience in bringing products to the market (C_{pat} , C_{prod} , D_{pat} , C_{prod}), referred to as weak players. Significant investments are needed here to organize a new production line (only subclasses of organizations IIb and some organizations of subclass Ib from Western Europe and the USA are ready for this), but this will be of great importance for the regional development, as it helps to create new jobs. It is also promising for these regions to expand the production of substitute goods (mainly for organizations of foreign origin of subclass Ia, IIa) and complementary goods (for organizations of subclass IIIa, IIIb).

In addition, Type 5 competency profile was formed to identify the regions that do not specialize in the production of antidiabetic drugs (D_{pat} , D_{prod}). Entry into such regions may be advisable only within the framework of a government program for the regional development (for example, for remote regions). In this case the decision on the localization of production can be made only based on studies of the market characteristics of the region (transport accessibility, costs of supporting processes, attractiveness of the region for qualified personnel). Only companies that already have experience in the Russian market can localize their production in the regions, such as subclass IIa organizations located in other regions, especially companies with extremely low production costs (for example, Chinese and Indian generic companies that previously successfully exported products to the Russian market).

The technological competencies formed in the region determine competitive and/or cooperative behaviour models of organizations that intend to localize production in this region for further marketing of products on the domestic pharmaceutical market. Implementation of the marketing function by the organizations at the level of a single region is not economically feasible due to the complex regulatory requirements for products. Therefore, the model of competitive behaviour of a foreign organization is practically independent of regional production factors, while the model of cooperative behaviour is largely determined by regional characteristics and should take into account the profile of technological competencies at the level of a specific region.

In order to select a competitive or cooperative behaviour model, an organization should take into account their economic and geographical characteristics, in particular, the regional distribution of production capacities and the ratio of drugs of foreign and domestic origin in the range of products.

Regional analysis of economic, geographical, competitive and cooperative characteristics of the commercial organizations

We consider the regional basis of the commercial organizations' localization in combination with an analysis of the presence of scientific and technical cooperation, including the presence of joint ownership of the exclusive right on a drug. Collaborative relationships between AstraZeneca and Bristol-Myers, Novo Nordisk, Merck & MSD and Novartis were identified. Licensed products are being manufactured under the localized production of Ranbaxy and Sun Pharmaceuticals Industry, KhimRar and Satereks, Marvel Lifesciences and Pharmstandard.

The highest performance indicators are characteristic for the organizations in the Russian geographic cluster, on the production facilities of which 112 products of the considered therapeutic profile are produced. These products are allocated within 89 trade names, which is half of the total number of trade names available on the Russian pharmaceutical market. The product category is distributed between 10 localized foreign organizations (27.7 % of the nomenclature of antidiabetic drugs on the market) and 24 domestic organizations (72.3 % of the nomenclature).

Table 2

Production branches localization in the regions of the Russian Federation and the number of products

Region	Number of Trade Names (TN)	The number of organizations and their trade nomenclature		The share of domestic production, %
		Foreign organizations localized in the Russian Federation (class II)	Russian organizations (class III)	
Moscow and Moscow region	38	5 org., 12 TN	9 org., 26 TN	68,4
Irkutsk region	9	—	1 org., 9 TN	100,0
Kaluga region	9	2 org., 8 TN	1 org., 1 TN	11,1
Saint Petersburg and Leningrad region	8	—	5 org., 8 TN	100,0
Kursk region	7	—	1 org., 7 TN	100,0
Republic of Bashkortostan	6	1 org., 2 TN	1 org., 4 TN	66,7
Oryol region	6	1 org., 6 TN	—	0,0
Samara region	6	—	1 org., 6 TN	100,0
Tomsk region	5	1 org., 1 TN	1 org., 4 TN	80,0
Kurgan region	4	—	2 org., 4 TN	100,0
Penza region	4	—	1 org., 4 TN	100,0
Sverdlovsk region	3	—	1 org., 3 TN	100,0
Rostov region	2	—	1 org., 2 TN	100,0
Kirov region	1	1 org., 1 TN	—	0,0
Lipetsk region	1	—	1 org., 1 TN	100,0
Perm region	1	—	1 org., 1 TN	100,0
Tyumen region	1	1 org., 1 TN	—	0,0
Chelyabinsk region	1	—	1 org., 1 TN	100,0

The parameter that impacts the ranking of regions (Table 2) is the productivity of organizations localized in a particular region, which was determined by the breadth of the manufactured antidiabetic drugs range.

The regions in which Russian full-cycle organizations are located are characterized by a high share of domestic products, which indicates the priority of the strategic objective of drugs import substitution aimed at increasing the national drug safety.

The rating can be presented in the form of a heat map or matrix according to the characteristics of organizations localized in a particular region, or by patent and product ranks of these organizations. Below we present a variant of the heat map of innovative and technological development of the antidiabetic drugs production in the regions according to the average-weighted patent and registration characteristics of the product ranges manufactured at localized production capacities in the region (Table 3). This heatmap characterizes the competitive profiles of the regions (a kind of competency threshold for the region's entry).

The intensity of shading of the heat map's cells corresponds to the specialization of production localized in the region associated with the product and technological innovations development and their launching to the Russian market. The regions in which full-cycle foreign productions are localized (Kaluga, Moscow, Oryol region) have the highest level of competencies. A high proportion of existing patents in the Moscow, Sverdlovsk and Chelyabinsk regions demonstrates the successful experience in the development and implementation of domestic innovations. Moreover, it suggests the feasibility of further development of these competencies in the mentioned regions, including through increased cooperation activity, which might contribute to the development of their own competencies and strengthen the economy of the region.

Heat map of R&D competencies of the drug manufacturing organizations in the regions of the Russian Federation

Region	Average-weighted characteristic of the regions' technological competencies based on relative patent and product indicators of the localized organizations									
	Patent indicators					Product indicators				
	Category ($ABCD_{pat}$)	Patent rank	Contribution to the total number of patents, %	The share of valid patents in the portfolio of organizations, %	The average lifetime of patents, years	Category ($ABCD_{prod}$)	Product rank	Contribution to the total number of drugs INN, %	Contribution to the total number of trade names, %	The share of innovation in the portfolio of organizations, %
Irkutsk region	D	—				B	4	14,81	4,49	
Kaluga region	A	2	17,60	57,45	10,70	A	2	12,96	4,68	20,00
Kirov region	C	6	7,12	15,79	8,70	B	5	9,26	2,81	5,71
Kurgan region	C	8	0,37		10,00	C	14	1,85	0,56	1,43
Kursk region	D	—				A	3	18,52	5,62	
Saint Petersburg and Leningrad region	C	5	1,50	25,00	12,00	C	13	3,70	1,12	1,43
Lipetsk region	D	—				C	12	3,70	1,12	
Moscow and Moscow region	A	1	7,30	71,23	12,33	B	7	6,70	2,38	8,21
Oryol region	B	3	23,60	23,81	9,20	A	1	16,67	6,18	14,29
Penza region	C	9	0,37		7,00	C	11	3,70	1,12	1,43
Perm region	D	—				C	16	1,85	0,56	
Republic of Bashkortostan	D	—				B	6	11,11	3,37	
Rostov region	D	—				C	15	1,85	1,12	
Samara region	D	—				C	10	9,26	2,81	
Sverdlovsk region	D	7	0,75	100,00	9,00	B	9	5,56	1,69	4,29
Tomsk region	D	—				B	8	11,11	3,37	
Tyumen region	D	—				C	17	1,85	0,56	
Chelyabinsk region	B	4	2,25	100,00	9,00	C	18	1,85	0,56	1,43
Average	—	—	6,76	56,18	9,77	—	—	7,57	2,45	6,47
Median	—	—	2,25	57,45	9,20	—	—	6,13	2,03	4,29

Conclusions

We have selected the indicators of product and technological development of organizations based on the study of literary sources and actual data specified in patents and drug registration certificates was made. Additionally, we have proposed synthetic and categorical indicators characterizing the competencies of organizations at the regional level.

For the first time, methodological approaches to analysing the product and patent portfolios of organizations were developed. They are used to assess the level of the organizations' innovative and technological development and present the technological competency profile of the region.

Further, we have substantiated the selection of five enlarged regional competency profiles, which are characterized by similar opportunities and threats for new pharmaceutical market players. It has been shown that the selected profiles determine the models of the organizations' cooperative behaviour.

The commercial organizations were ranked and categorized by the level of scientific and technological competencies in the field of developing antidiabetic drugs and launching them in the market, which enabled assessment of the prospects for regional development.

It has been revealed that the model of cooperative behaviour is largely determined by regional characteristics and should take into account the profile of technological competencies at the level of a specific region. The model of competitive behaviour of organizations in the Russian pharmaceutical market is to a much lesser extent based on regional characteristics of localized production.

The use of methods for constructing patent and product ratings of the regions and their categorization with the identification of typical behavioural models contributes to the rapid and effective search and implementation of technological capabilities aimed at increasing the availability and quality of domestic pharmaceutical products.

Applicability

The research findings are of practical importance for specialists of the strategic development departments, analytical and patent departments and managers at various levels. The results contribute to the optimization of the following processes:

- development of defensive or offensive patent strategies for organizations involved in research and production activities in the competitive market;
- analysis of the competitive profile and innovative potential of organizations localized in one region and specializing in similar fields;
- selection of a competitive or cooperative behavioural model of the organization in the face of uncertainty of the external environment and insufficient amount of open data;
- determination of the prospects for long-term cooperation of an organization with technological leaders in the selected field (through joint patenting, localization of part of the licensed production cycle) at the regional and industry levels, which is especially important for implementing the concept of national drug safety and, as a result, increasing accessibility of socially significant drugs for the population.

References

1. Dubois, P., Mouzon, O., Scott-Morton, F. & Seabright, P. (2015). Market size and pharmaceutical innovation. *The RAND Journal of Economics*, 46(4), 844–871. DOI: <https://doi.org/10.1111/1756-2171.12113>.
2. Branstetter, L., Chatterjee, C. & Higgins, M. J. (2016). Regulation and welfare: evidence from paragraph IV generic entry in the pharmaceutical industry. *The RAND Journal of Economics*, 47(4), 857–890. DOI: <https://doi.org/10.1111/1756-2171.12157>.
3. Grabowski, H. (2004). Are the economics of pharmaceutical research and development changing? Productivity, patents and political pressures. *Pharmacoeconomics*, 22(2), 15–24. DOI: 10.2165/00019053-200422002-00003.
4. Coccia, M. (2017). Sources of technological innovation: Radical and incremental innovation problem-driven to support competitive advantage of firms. *Technology Analysis & Strategic Management*, 29(9), 1048–1061.
5. Nikolopoulos, K., Khamash, M., Buxton, S. & Stern, P. (2016). Forecasting branded and generic pharmaceuticals. *International Journal of Forecasting*, 32(2), 344–357.
6. Jekunen, A. (2014). Decision-making in product portfolios of pharmaceutical research and development—managing streams of innovation in highly regulated markets. *Drug Design Development and Therapy*, 8, 2009–2016. DOI: 10.2147/DDDT.S68579.
7. Ivanov, N. I. & Foukova, D. Yu. (2009). Konkurentnyy analiz: benchmarking [Benchmarking vs. Competitive analysis]. *Ekonomicheskii analiz: teoriya i praktika [Economic analysis: theory and practice]*, 22, 53–55. (In Russ.)
8. Kadirov, E. A. (2018). Primenenie benchmarkinga kak innovatsionnoy marketingovoy tekhnologii na farmatsevticheskom rynke [Benchmarking as an innovative marketing technology on the pharmaceutical market]. *Obshchestvo: Politika, ekonomika, pravo [Society: Politics, Economics, Law]*, 2, 29–33. (In Russ.)
9. Dahooie, H., Zavadskas, E. K., Firoozfar, H. R., Vanaki, A. S., Mohammadi, N. & Brauers, W. K. M. (2019). An improved fuzzy MULTIMOORA approach for multi-criteria decision making based on objective weighting method (CCSD) and its application to technological forecasting method selection. *Engineering Applications of Artificial Intelligence*, 79, 114–128.
10. Dirnberger, D. (2011). A guide to efficient keyword, sequence and classification search strategies for biopharmaceutical drug-centric patent landscape searches — A human recombinant insulin patent landscape case study. *World Patent Information*, 33, 128–143.
11. Lee, Ch., Kwon, O., Kim, M. & Kwon, D. (2018). Early identification of emerging technologies: A machine learning approach using multiple patent indicators. *Technological Forecasting & Social Change*, 79, 291–303.
12. Huang, C., Lin, H. H., Wan, J., He, C. & Hu, Y. (2016). Research and Development of Hepatitis B Drugs: An Analysis Based on Technology Flows Measured by Patent Citations. *PLoS One*, 11(10), 1–17. DOI: 10.1371/journal.pone.0164328.
13. Pereira, C. G., Lavoie, J. R., Garces, E., Basso, F., Dabić, M., Portoa, G. S. & Daimb, T. (2019). Forecasting of emerging therapeutic monoclonal antibodies patents based on a decision model. *Technological Forecasting & Social Change*, 139, 185–199.
14. Fabry, B., Ernst, H., Langholz, J. & Koster, M. (2006). Patent portfolio analysis as a useful tool for identifying R&D and business opportunities — an empirical application in the nutrition and health industry. *World Patent Information*, 28, 215–225.
15. Kumar P. (2018). Patent research as a key strategy tool. *Pharm Exec Magazine*, 9. Retrieved from: <http://www.pharmexec.com/patent-research-key-strategy-tool> (Date of access: 10.01.2019).
16. Song, C. H. & Han, J.-W. (2016). Patent cliff and strategic switch: exploring strategic design possibilities in the pharmaceutical industry. *Springerplus*, 5(1), 692. DOI: 10.1186/s40064-016-2323-1.
17. Yu, X. & Zhang, B. (2017). Obtaining advantages from technology revolution: A patent roadmap for competition analysis and strategy planning. *Technological Forecasting & Social Change*, 11. DOI: <http://dx.doi.org/10.1016/j.techfore.2017.10.008>.

18. Hsueh, C.-C. & Chen, D.-Z. (2015). A taxonomy of patent strategies in Taiwan's small and medium innovative enterprises. *Technological Forecasting & Social Change*, 92, 84–98.
19. Milanez, D. H., Faria, L. I. L., Amaral, R. M. & Gregolin, J. A. R. (2017). Claim-based patent indicators: A novel approach to analyze patent content and monitor technological advances. *World Patent Information*, 50, 64–73.
20. Tikhanov, E. A., Krivorotov, V. V. & Chepur, P. V. (2016). Analiz i sistematizatsiya metodov otsenki konkurentosposobnosti [Analysis and systematisation of enterprises competitiveness evaluation methods]. *Fundamentalnye issledovaniya [Fundamental research]*, 10(3), 647–651. (In Russ.)
21. Grek, P. V. (2007). Primenenie marketingovykh instrumentov v usloviyakh kategoriynogo menedzhmenta [Marketing assessment application in the field of category management]. *Remedium*, 1, 27–30. (In Russ.)
22. Grishin, A. V. & Krasheninina, A. N. (2010). Innovatsionnaya Sistema upravleniya tovarnymi zapasami aptechnoy organizatsii [Drug stocks management: innovative system]. *Novaya apteka [New Pharmacy]*, 8, 10–15. (In Russ.)
23. Parnell, J. A., Long, Z. & Lester, D. (2015). Competitive strategy, capabilities and uncertainty in small and medium sized enterprises (SMEs) in China and the United States. *Management Decision*, 53(2), 402–431. DOI: <https://doi.org/10.1108/MD-04-2014-0222>.
24. Koufteros, X. A., Vonderembse, M. A. & Doll, W. J. (2002). Integrated product development practices and competitive capabilities: the effects of uncertainty, equivocality, and platform strategy. *Journal of Operations Management*, 20(4), 331–355. DOI: 10.1016/S0272-6963(02)00018-9.
25. Azzaro-Pantel, C. (2018). New Product Development and Supply Chains in the Pharmaceutical Industry. *Computer Aided Chemical Engineering*, 41, 1–26.
26. Marques, C. M., Moniz, S. & Sousa, J. P. (2018). Strategic decision-making in the pharmaceutical industry: A unified decision-making framework. *Computers & Chemical Engineering*, 119, 171–189.

Authors

Sergey Vsevolodovich Kortov — Doctor of Economics, PhD in Physics and Mathematics, Associate Professor, First Vice-Rector, Ural Federal University; Scopus Author ID: 6507987690 (19, Mira St., Ekaterinburg, 620002, Russian Federation; e-mail: s.v.kortov@urfu.ru).

Dmitry Borisovich Shulgin — Doctor of Economics, PhD in Physics and Mathematics, Associate Professor, Head of the Intellectual Property Center, Head of the Department of Intellectual Property Management, Ural Federal University; Scopus Author ID: 57190007502 (19, Mira St., Ekaterinburg, 620002, Russian Federation; e-mail: d.b.shulgin@urfu.ru).

Aleksey Vladimirovich Rodnin — PhD student, Assistant Professor, Department of Intellectual Property Management, Ural Federal University (19, Mira St., Ekaterinburg, 620002, Russian Federation; e-mail: a.v.rodnin@urfu.ru).

Alisa Alekseevna Karimova — PhD in Pharmaceutical Sciences, Assistant Professor, Department of Management and Economics of Pharmacy, Pharmacognosy, Ural State Medical University (3, Repina St., Ekaterinburg, 620028, Russian Federation; e-mail: pharm.usmu@gmail.com).