

**T. Pyatchanyna,
A. Ogorodnyk,
P. Melnik-Melnikov**

METHODOLOGICAL APPROACHES TO PATENT RESEARCH IN THE FIELD OF BIOMEDICAL SCIENCES

*R.E. Kavetsky Institute of Experimental Pathology, Oncology and Radiobiology,
National Academy of Sciences of Ukraine
Department of Research Management and Innovation
Vasylkivska str., 45, Kyiv, 03022, Ukraine
e-mail: kassmail@ukr.net,*

*Інститут експериментальної патології, онкології і радіобіології
ім. Р.С. Кавецького НАН України
відділ менеджменту наукових досліджень та інновацій
Васильківська вул., 45, Київ, 03022, Україна*

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Ключові слова: *патентні дослідження, науково-технічна розробка, об'єкт господарської діяльності, бази даних, медико-біологічні науки, наукова установа, вищий навчальний заклад*

Ключевые слова: *патентные исследования, научно-техническая разработка, объект хозяйственной деятельности, базы данных, медико-биологические науки, научное учреждение, высшее учебное заведение*

Abstract. Methodological approaches to patent research in the field of biomedical sciences. Pyatchanyna T., Ogorodnyk A., Melnik-Melnikov P. *Patent research in the field of biomedical sciences (BMS) allows to give an objective assessment of the novelty and technical and economic level of the developed object of economic activity, to identify the most promising objects of economic activity, to identify competitive trends in the analyzed industry, to use the best achievements of world science, in the course of scientific research (SR), timely protect own technological and technological solutions with patents in Ukraine and abroad. The purpose of the article is to optimize methodological approaches to conducting patent research in the field of biomedical sciences on the basis of analysis of patent and scientific and technical databases. The fulfillment of the patent researches requires the use of compulsory methodological approaches, which are developed on the basis of DSTU 3575-97 "Patent Research: Key Provisions and Procedure". At each stage of the implementation of the SR, the algorithm for the patent researches, which must be followed in order to ensure the perspective of the development of object of economic activity, its legal protection, and competitiveness has been developed. The methodical approaches to conducting the patent researches in the field of BMS are determined on the basis of analysis of patent and scientific and technical databases, which allow to reveal competitive directions in the field of BMS, identify the most promising ones, give an objective assessment of novelty and technical and economic efficiency of SR; to use the most outstanding achievements of the world science during SR; timely protect own technical and technological decisions by patents in Ukraine and abroad.*

Реферат. Методичні підходи до проведення патентних досліджень у галузі медико-біологічних наук. П'ятчаніна Т.В., Огородник А.М., Мельник-Мельников П.Г. *Патентні дослідження в галузі біомедичних наук (БМС) дозволяють дати об'єктивну оцінку новизни і техніко-економічного рівня розробленого об'єкта економічної діяльності, визначити найбільш перспективні об'єкти економічної діяльності, виявити конкурентні тенденції в аналізованих підприємствах, використовувати в процесі НДДКР найкращі досягнення світової науки, своєчасно захищати власні технологічні та технологічні рішення з патентами в Україні та за кордоном. Виконання патентних досліджень вимагає застосування обов'язкових методологічних підходів, які розробляються на основі ДСТУ 3575-97 «Патентні дослідження: ключові положення та порядок». На кожному етапі реалізації НДР розроблено алгоритм патентних досліджень, якого необхідно дотримуватися для забезпечення перспективи розвитку об'єкта економічної діяльності, її правового захисту та конкурентоспроможності. На основі аналізу патентних і науково-технічних баз даних, які дозволяють виявити конкурентні напрямки в галузі БМС, визначити найбільш перспективні, дати об'єктивну оцінку, визначаються методичні підходи до проведення патентних досліджень у сфері БМС, новизни та техніко-економічної ефективності НДДКР; вони дозволяють використовувати найбільш видатні досягнення світової науки під час НДДКР; своєчасно захищати власні технічні та технологічні рішення патентами в Україні та за кордоном.*

Today, progress and competitiveness in the field of BMS are achieved through the development of innovative biological, medical, pharmaceutical science-intensive technologies and scientific and technical developments (STD), which are the result of the implementation of scientific research and projects. The rapid development of medical and biological science and the demand for research results in this area promotes commercialization and acceleration of the pace of implementation of a significant number of innovative products into health care practice, which increases the efficiency of diagnosis and treatment, refusal to use ineffective approaches to prevention, prolongs the life of patients and raises its quality.

The use of intellectual property in the management and production activities of research institutions (RI) and universities is carried out at all stages of the life cycle (LC) of object of economic activity [6]. It is known, that patent documentation is several years out by other types of publications, is not duplicated in other sources of information, reliable and confirmed by the conclusions of the state scientific and technical expertise, covers all branches of science and is published more than in 80 countries of the world. A patent is the sole source of information on the scope of patent holders' rights. In addition, patent documents are a valuable source of technical and commercial knowledge about technology development, market trends and corporate assets that are presented in the form of an innovative product [4, 10, 11].

Therefore, the search for methodological approaches and increase of the productivity of conducting patent research in the field of BMS is an important factor in optimizing the patent and licensing strategy of RI and universities, and therefore, an increase in the implementation of potential of domestic scientific and technical medical and biological developments.

Objective – optimization of methodical approaches to conducting patent research in the field of biomedical sciences on the basis of analysis of patent and scientific and technical databases.

MATERIALS AND METHODS OF RESEARCH

In the work for analysis modern sources of information and scientific communication – scientific articles, materials of periodicals, Internet resources, patent databases, regulatory documents are used. The methodological basis of the study was the methods of structural-logical and comparative content analysis of international and national patent databases and the synthesis of the results of the analysis. Search for patent databases containing the patents for scientific and technological innovations

in the field of biomedical sciences was conducted in the Internet by the key words, key constructions and indexes of the IPC [1].

RESULTS AND DISCUSSION

In most developed countries, patent and information analysis is an integral part of the scientific research (SR) and the basis of competitive analysis [3, 8]. Restrictions in the conducting of information and analytical search by traditional sources of information, such as publications in scientific and technical journals and proceedings of scientific forums, without a thorough study of patent documents can lead to the loss of a significant part of scientific and technical knowledge, which will definitely affect the quality of research, the implementation potential of the scientific and technological revolution and their level of commercialization [4].

European Patent Office studies have shown that from 70% to 90% of the unique information contained in patent documents is never publicly disclosed [11]. Therefore, analytical research of patent information is used to generate new ideas and identify industries where they can find application. In the modern world, patent information as a stable information stream was formed as a result of regulated by law relations that arise in the creation and use of inventions, industrial designs and utility models [8, 10].

Patent research (PR) is a modern tool for analyzing the patentability of an intellectual property object, which allows to investigate the development of scientific and technological advances in various fields of science and technology.

In general, patent research allows to investigate the level of technology in connection with the object being claimed, as well as to determine the expediency of its legal protection; to minimize the risk associated with possible duplication of already existing technical solutions at the initial stage of development of a potential object of patenting, thereby determining the compliance of the object of patenting with such a criterion of patentability as "novelty"; to receive information on the technical solutions or technologies that are the subject of the study in order to further obtain a patent or license for an already patented decision; to identify the infringements of the rights of patent holders to industrial property objects; to analyze the conditions of unimpeded product sales in a particular country and exclude violations of the rights of third parties possessing patents valid in the territory of these countries; to develop a marketing strategy for identifying the most promising areas of activity, identify potential competitors, to determine the directions of their activities and choose own market

niche; to study trends in the development of a particular type of technology [5].

The following main types of PR are subject, nominal (or branded), numbering, search for Patent Family [7].

The main and most frequently used search involves the formulation of a technical task (the subject of a search), the choice of the categories of international patent classification, limitation of the thematic area of search, detection and analysis of related patent materials related to a certain time interval. The nominal (or branded) search complements the subject matter and is carried out in case when the name (s) of the inventor (inventors) or company names are known. The numerical search is carried out in case when the number of the security document is known, which makes it possible to find out other information. The search for Patent Family is conducted in order to identify patents issued in any country and then patented in other countries to the same invention. Patent Family is a very important concept for both the legal protection of inventions and the identification of strategic markets of companies. If, at the time of application or obtaining a patent, the applicant indicates the countries to which applications for the protection documents will be submitted, this indicates the seriousness of business intentions in these countries. Therefore, the market entry in this country (countries) is a priority.

In order to define the full set of documents that form Patent Family, it is necessary to examine all applications, regardless of the country, or at least their maximum number. Patent Family appears because during the transfer of the international patent to the national phase, the patent document (basic patent document) is assigned its own national number, different from the number assigned by the patent office of the country where the application was initially submitted. During Patent Family research, the priority number is taken as the basis.

The complexity, completeness, reliability, as well as analytical capabilities of the patent research depend directly on the sources of information used. Thus, the patent databases of the national (Ukraine) and world (European Patent Office, Eurasian Patent Organization, WIPO, US, CIS, Canada, Japan, etc.) patent offices provide official information on patents and, therefore, are the most reliable source of legal information.

In Ukraine, patent research is mandatory for economic entities, which are wholly or partially financed from the state budget, which fully relates to RI and universities, whose activities are in the biomedical field. Therefore, the state standard of

Ukraine - DSTU 3575-97 "Patent Research. Basic Provisions and Procedure" (hereinafter DSTU) of 01.01.1998 indicates the state's interest in the creation of perfect competitive products [2].

In accordance with DSTU, there is a need for a clear statement of the problem, which is studied during patent research, depending on the LC stage of studied object. The most important are the results of the patent research, which are carried out at the initial stages of scientific research, i.e., for forecasting and long-term planning.

The specificity of the patent research in the field of BMS is that the object of economic activity in this field of science is most often of the following types - the method, compound, strain of the microorganism. With regard to the Patent Family in the field of BMS, it is important to take into account some of the features of its implementation: the search, selection and analysis of patent and information materials that are relevant to the research that is planned; determination of the technology readiness level, determination of factors influencing the received negative results, determination of the possibility of obtaining new results; determination of the degree of coincidence and the discrepancy between the essential characteristics of the object of economic activity and the identification of analogues of patents; determining the probability of finding the necessary information materials.

Patent researches are carried out at all stages of the LC of object of economic activity, in particular, when the idea and planning of the scientific research takes place; at the stage of research, development and creation of object of economic activity; protection and commercialization of object of economic activity. The patent researches at each stage are carried out taking into account the results of the previous stage of the patent research, as well as taking into account new sources of information that became known at the time of the beginning of this stage.

The stage of the LC object of economic activity "Research and development justification" lasts from the moment the idea creation till the feasibility of creating of object of economic activity substantiation. At this stage, forecasting, prospective and ongoing planning and development of scientific projects are carried out. The implementation of this phase consists of successive interconnected steps: first, the development of the SR plan is being carried out; the object of the search is defined - as a certain aspect of the object - the novelty, purity of patent research, the level of technology, patentability, which is the purpose of the search; the search object is determined - a technical solution characterized by

the structure, properties and application; determined by the purpose of the patent research. For an invention (utility model), as a rule, the purpose of a patent research is to find analogues and identify the prototype closest to the developed invention (utility model) and to determine the fact that at the moment no such technical solution exists. The final task of this stage is the development of search regulations.

The stage "Development of object of economic activity" deals with changing the status of object of economic activity - from the formulation of the SR technical task requirements on the creation (modernization) of object of economic activity to their integration into new (upgraded) research samples, materials, services, i.e., to their materialization. At this stage, the search and selection of patent and other scientific, technical and business information is being performed; systematization and analysis of the selected information depending on the type of work performed during the implementation of the patent research; analysis of documentation, which leads to the selection of inventions that are of interest to the developer.

At the stage of the LC of object of economic activity "Execution and Completion of the SR" - the technical level and novelty of the obtained results are determined; the situation regarding the use of rights to industrial property objects (dynamics of patenting, mutual patenting, search of patent analogues, licensing activity of companies); detection of infringements of the rights of protection document owners to industrial property objects; results generalization and compiling a report on the patent researches.

Thus, when carrying out the SR in the field of BMS, the patent research at all stages of the object of economic activity is mandatory for economic entities that are wholly or partially financed from the state budget. The algorithm of conducting a patent research in the field of BMS should take into account the arrangement specifics of national and international patent databases, provide for different methods of search, and include the most informative databases to determine the state-of-the art level of particular technology.

Patent documentation in the standardized form of documents is published by official agencies - this increases the degree of reliability and completeness of information reflected in protection documents [10]. The primary sources of patent information are the official bulletins of the patent offices of different countries. In Ukraine, the state-owned enterprise "Ukrainian Institute of Intellectual Property" (<http://www.uipv.org>) is the official body that publishes information on applications, changes in

applications, issued patents and refusals to issue a patent. Information about a specific patent may be published in several subsequent bulletin numbers reflecting changes in the application (patent) during its entire term of validity (in Ukraine - 10 years of validity of a declarative patent and 20 years for a patents on inventions) [7]. Patent information of national patent offices is published not only in official bulletins, but also on their websites. The full list of patent offices that provide patent information can be found on the website of the World Intellectual Property Organization (WIPO) (<https://www.wipo.int/members/en/>).

The web resource of each patent office has its own search engine and the constructive principles of working with documents. The largest collection of free patent information includes the resources of the European Patent Organization (EPO-[espacenet](http://ep.espacenet.com), <http://ep.espacenet.com>), WIPO, Japan, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, and UK.

The USA offers access to the full-text database of patents since 1976, abstract database of patents since 1976 and the database of trademarks. The search is based on bibliographic data and the text of the document, as well as viewing facsimile copies of the pages of the found documents in a graphic format (<http://www.uspto.gov>).

The WIPO database "PATENTSCOPE" (<https://www.wipo.int/patentscope/ru/>) allows one to get the full text of the international applications filled under the Patent Cooperation Treaty (PCT) from the first day of their publication, as well as with the patent documents of national and regional patent offices of member states. As of 2018, data of 57 national or regional offices are represented in the PATENTSCOPE database. It is also the only database that provides access to the full collection of PCT international applications, as well as collections of regional and national patents.

Today's the largest commercial companies, which create patent, scientific and technical databases in the field of BMS are: Derwent (UK), Japio (Japan), IFI Claims Patent Services (USA), Micro-Patent and others.

Derwent (<http://www.derwent.com/>) has been the world leader in the production of patent and scientific and technical databases since 1982. The DB contains scientific developments in the field of BMS and covers such areas as gene and cellular engineering, engineering enzymology, biotechnology of medicines, biotechnology of food additives and

creation of biotechnological equipment, as well as biotechnology methods in environmental protection.

Thus, national and international databases provide complete information in each scientific field. When conducting a patent researches in the field of BMS it is expedient to use search in the patent, scientific and technical databases - it gives an opportunity to get information about the novelty of object of economic activity, the level of technology, the search for patent analogues, prospective commercial solutions in medicine and biology, competitiveness, and also helps to identify trends in formation of new scientific directions of research and can serve as a forecast of new scientific directions.

CONCLUSIONS

Patent research in the field of medical and biological sciences at all stages of the life cycle of an object of economic activity is mandatory for economic entities, which are wholly or partially financed from the state budget. The conduct of patent research requires the use of methodological approaches, which are determined on the basis of DSTU 3575-97 "Patent Research. Basic Provisions and Procedure." For each stage of research work, its algorithm of patent research is developed, which should be followed in order to ensure the promising outlook of the development of object of economic activity, its legal protection, and competitiveness.

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