UDC 330.341.1
JEL classification: L65, O31

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FEATURES OF COMMERCIALIZATION IN BIOTECHNOLOGY

ОСОБЛИВОСТІ КОМЕРЦІАЛІЗАЦІЇ РЕЗУЛЬТАТІВ БІОТЕХНОЛОГІЧНОЇ ПРОМИСЛОВОСТІ

The purpose of the study is to determine the specific features of the commercialization of scientific and engineering developments in the field of biotechnology. According to the goal, the main tasks are: to find out specific features of biotechnology production and determine their impact on the commercialization of scientific and technological developments in the field of biotechnology; to analyse existing forms of commercialization of innovative developments and to find out the possibility of their application in biotechnology; to outline the features and related problems of commercialization of scientific and engineering developments in the biotechnology industry.

The article defines commercialization, consider on commercialization of scientific and technical innovative developments. It demonstrates urgency and necessity of innovative developments commercialization as an answer to the growing needs of consumers and market evolution. The study argues the interdisciplinary of biotechnology and its distribution in various spheres of life through colour classification. It determines the features of commercialization in biotechnology. The author describes the main characteristics of biotechnologies: complexity of the structure of biotechnological products, the complexity of production, the imperfection of quality control methods, and the lack of clinical history of drugs. She insists on their great influence on the commercialization of developments of the industry. The article shows that all the characteristics of biotechnologies can be divided into those that have a direct and indirect impact on their commercialization. It enumerates the forms of commercialization of scientific and technical developments: use in their own production, leasing, engineering, franchising, industrial cooperation, license agreements and consider on the possibility of their application in biotechnology. Not all forms of commercialization can be applied in the industry and franchising definitely can't. The scientific novelty of this study is to substantiate the influence of the characteristic features of the industry on the processes of commercialization in biotechnology, the choice of forms of commercialization, the definition and systematization of problems, the solution of which will simplify the processes of commercialization of biotechnological developments.

Keywords: Commercialization, scientific and technical developments, innovation development, biotechnology.

Метою статті є визначення галузевих особливостей комерціалізації науково-технічних та інженерних розробок в галузі біотехнології. Відповідно до поставленої мети основними

завданнями є: з'ясувати ознаки біотехнологічних виробництв та визначити їх вплив на комерціалізацію науково-технічних розробок в галузі біотехнології; проаналізувати існуючі форми комерціалізації інноваційних розробок та з'ясувати можливість їх застосування у біотехнології; окреслити особливості та пов'язані з ними проблеми комерціалізації науково-технічних та інженерних розробок в галузі біотехнології.

Стаття визначає поняття комерціалізації, розглядає процес комерціалізації науково-технічних та інноваційних розробок. Доводить актуальність і необхідність комерціалізації інноваційних розробок як відповідь на зростаючі потреби споживачів та розвитку ринку в цілому. Робота вказує на міждисциплінарність біотехнології як науки та її поширення у різні сфери життя суспільства, через «кольорову» класифікацію. Визначено особливості комерціалізації в сфері біотехнологічної промисловості. Автор визначає головні характеристики біотехнологій: складність структури біотехнологічних продуктів, складність виробництв, недосконаліть методів контролю якості, відсутність клінічної історії у препаратів, вказує на їхній вплив на комерціалізацію розробок в галузі. У статті вказується, що особливості галузі можна умовно поділити на ті, що мають безпосередній та опосередкований вплив на комерціалізацію. В дослідженні представлені існуючі форми комерціалізації науково-технічних розробок, а саме: використання у власному виробництві, лізинг, інжиніринг, франчайзинг, промислова кооперація, ліцензійні угоди, а також розглядаються можливості застосування їх у сфері біотехнології. Не всі форми комерціалізації можливо застосовувати в даній галузі, особливо це стосується такої форми як франчайзинг. Наукова новизна даного дослідження полягає в обґрунтуванні впливу характерних ознак галузі на процеси комерціалізації в біотехнології, вибору форм комерціалізації, визначенні та систематизації проблем, вирішення яких дозволить спростити процеси комерціалізації біотехнологічних розробок.

Ключові слова: комерціалізація, науково-технічні розробки, інноваційні розробки, біотехнологія.

Introduction. Scientific and technical developments and innovative activity are related to the creation, implementation and distribution of research results for purpose of products range expanding and quality and technology improvements, that can deliver competitive advantages of the product and reduce its manufacturing and consumption cost.

Commercialization of the results of scientific and technical developments is an important aspect of activity and development in any industry. Education, science, technology are constantly evolving as well as the needs of society. The consumer demands better, more efficient, more economical, high-quality products and technologies. Therefore, commercialization of innovative products and engineering developments is an important aspect in economic activity.

Commercialization is the process of transforming the result of scientific activity into a product [1]. This is the way of building a business, based on the results of scientific and technical research. Often, commercialization is defined as a process of finding and attracting investment for the implementation of the results of research, but achieving the economic effect of this introduction is only possible if the future product is competitive.

The work of many foreign and Ukrainian scientists is devoted to solve problems of commercialization of innovative developments [2-10]. In particular, Drucker P., Schumpeter J., Romanovsky O., Gorbulin V., Mukhopad V., Shuba I., Polyakova E., Olefirenko O., Stanislavik O. and others investigate the issues of organizing the process of commercialization, innovations transfer, management processes and problems of the efficiency of the innovation activity of business entities. With the varying degrees of theoretical and practical coverage in their works, the essence of the notion of commercialization, the ways and methods of commercialization, the problem of commercialization of innovative products in Ukraine are disclosed.

At the same time, insufficient attention is paid to the sectoral features of commercialization of innovative developments, in particular in the biotechnology industry.

Setting objectives. The purpose of the study is to determine the specific features of the commercialization of scientific and engineering developments in the field of biotechnology. According to the goal, the main tasks are:

- To find out specific features of biotechnology production and determine their impact on the commercialization of scientific and technological developments in the field of biotechnology;

- To analyze existing forms of commercialization of innovative developments and to find out the possibility of their application in biotechnology;

-To outline the features and related problems of commercialization of scientific and engineering developments in the biotechnology industry.

Methodology. During the research, general scientific and applied scientific research methods were used, namely:

- Method of analysis and synthesis - to distinguish the signs of biotechnological production and their impact on commercialization processes in the industry;

- Comparative method - to determine the possibilities of using certain forms of commercialization in the biotechnology industry;

- Logical method and method of generalizations - to provide relevant conclusions and practical recommendations for solving the problems of commercialization of scientific and technological developments in biotechnology.

Research results. Over the last decade, various biotechnologies have become widely used. The reason for this is the potential of their capabilities to solve the following global problems, in particular, healthcare. Biotechnologies are effectively used to create tools for the treatment of diseases and modern vaccines development; application of biofuels in power engineering, engines (which makes it possible to reduce anthropogenic impact on the environment); increase of productivity through protection of plants from harmful insects and weeds using the biological products of bacterial, viral and fungal nature; using the food crops with improved properties.

The features of the biotechnology industry are innovation, viability and the need for government support and regulation, since almost all the results and products of this industry require certification, standardization and licensing. Therefore, this is primarily the permissive activity that is carried out by economic entities within the norms and rules that are created by the state. Very often, the legal framework defined by law and aimed to improve the conditions for commercialization and the operation management in this area are separated from practice.

The development of the biotechnology industry involves several key areas, in particular, the use of biomass for the creation of alternative energy sources, the development of scientific foundations for the creation of new biotechnologies using molecular biology, genetic and cellular engineering, wastewater treatment with biological assets, the use of biological components in the pharmaceutical industry, the use of viruses to create new biotechnologies and to improve technology and equipment for the areas listed above.

Since biotechnology are used in various industries and affect many spheres of human life, the so-called "color" classification of biotechnology has been adopted in the world [11]:

- "red" biotechnology (more than 60% of world production) - is associated with the human health and the production of biopharmaceuticals;

- "green" (12% of world production) - is aimed at development and creation of genetically modified (GM) plants resistant to biotic and abiotic stresses. It defines modern methods of agriculture and forestry management;

- "white" - industrial biotechnology, which combines biofuel production, food biotechnology, chemical and oil refining industry;

- "gray" - related to nature conservation activities, water, soil and atmosphere cleaning;

- "blue" - associated with the use of marine organisms and raw materials.

Signs that are characterized by biotechnological production and products are [12]:

1. Complexity of the structure of biotechnological products (differences of organisms, obtaining methods, purification processes). Any minimal changes in the primary protein sequence and in its spatial organization are difficult to predict under biotechnology production. This affects the pharmacological activity of the target product, and thus complicates the standardization of biotechnology production.

2. The complexity of production (experimental data suggest that it is almost impossible to repeat any of the above stages of the production of a biotechnological product without knowing the protocol.[13] With minimal deviations in the production technology, the lack of management of the producers can cause changes in the characteristics of even the original biotechnological medicines).

3. The imperfection of methods of quality control of biotechnological products (modern, generally accepted methods for analyzing the structure of biotechnological products have proved to be unsuitable for the interpretation of the differences between these drugs in their clinical application (i.e., the active substances are identical and their effects differ). This requires the development of more sensitive analytical procedures that take into account the features of each biotechnological product).

4. An absence of clinical history in drugs, i.e. their immunogenicity (if the drug is "unsuccessful", it can lead to a decrease in the activity of the drug itself, which inevitably causes the complication of the disease).

The identified features have a direct and indirect effect on the processes of commercialization of innovative developments in the field of biotechnology. In particular, the complexity of the structure of biotechnological products and the complexity of production require high qualifications, knowledge and experience in the industry. That complicates the process of commercialization by attracting funds from the "party", as the available own resources are limited. The imperfection of quality control methods can affect the process of commercialization during implementation process, i.e. with the full or partial funds "injection", which may lead to the closure of the project. Immunogenicity of drugs that can be detected at the end of the commercialization process will lead to the closure of the project, and, therefore, the loss of the invested funds.

Another problem and specific feature of biotechnological developments is the size and performance of facilities for the production processes, as well as their cost.

As you know, the criterion for selection of scientific developments is profit, the level of competition, market potential, availability of resources, production capacity of the enterprise, the degree of risk, total costs, the period of return of investments and their profitability.

Developments in the biotechnology industry are characterized by significant investment, most of which spent on biotechnology machinery. That is, it is usually fund-raising production with a long production cycle (more than one year) and a long period of investment return (more than seven years). Therefore, the key role in the commercialization of innovations in biotechnology should be given to the government through various mechanisms of tax preferences for the enterprises of the sector, financing of various programs (usually on a competitive basis), subsidization of services on the commercialization of innovations and technologies and through the system of state orders (that does stimulate contract-based scientific studies).

Commercialization of the results of scientific developments involves their introduction into economic activity. This process is preceded by a difficult and intensive work on the development of a set of scientific, technical, marketing, financial, production documentation, obtaining a prototype and security documents for intellectual property, calculating and evaluating the efficiency, harmonizing the timing of implementation and funding phases.

To select the form and method of commercialization of scientific and technological developments in the biotechnology industry, it is necessary to analyze the existing forms of commercialization. Shub I.V. is submitting a systematic list of commercialization forms. [7]. He offers the following forms:

1. *The use in own production*. The essence of the form lies in the fact that the invention was created for its own purposes. The benefits of this method are the ability to avoid spending money and time on a searching for a buyer of development. It allows to keep a monopoly on the market of an innovative product, the ability to continuously control the production. A few disadvantages are present – a significant period of investment return, the need for significant material and financial costs to implement the invention;

2. *Leasing*. This is a form of commercialization, when the equipment acts as the object of intellectual development. The advantage of this form is the possibility of

obtaining additional profits when using the object in its own production, as well as the possibility of redeeming equipment at its final cost when the contract is expired;

3. *Engineering*, as a form of commercialization, provides engineering and consulting services of research, accounting and analytical nature, preparation of feasibility studies for projects, development of recommendations for the introduction of an innovative product;

4. *Franchising*. In this form of commercialization, the object of intellectual property is a sign for goods and services (brand). Due to brand information and franchisor business reputation guarantees, relatively quick profit is guaranteed at low cost;

5. *Industrial cooperation* involves the transfer of intellectual property rights of objects and engineering developments within a joint venture. The main function of co-operation is to minimize the level of business risk and production costs. Advantages include reducing the cost of deployment and the opportunity to enter new markets;

6. *The issue of licenses* is one of the most common forms of commercialization, which provides an additional profit from the patent holder from the sale of the license. Sale of a license allows solving problems in excess of demand for products over the volume of own production, if necessary, funds for improving production.

Therefore, there are various forms of commercialization, which are selected in accordance with the particular innovation object, financial and material capabilities of the owner, etc.

For biotech enterprises, almost all forms of commercialization of development, except for franchising, are acceptable. Franchising is not acceptable because in this form of commercialization the key element is the brand which is not common in biotech enterprises. The most appropriate form of use is in its own production, but the lack of its own resources for commercialization is possible. Then the sale of a license or leasing (in the case of engineering) may become an acceptable form.

The evaluation of the commercialization of intellectual property objects is based on the following principle: the introduction of scientific and technical developments creates costs that must be opposed to opportunities for increasing profits and the potential benefits to those who use this development.

Conclusions. *The scientific novelty* of this study is to substantiate the influence of the characteristic features of the industry on the processes of commercialization in biotechnology, the choice of forms of commercialization, the definition and

systematization of problems, the solution of which will simplify the processes of commercialization of biotechnological developments.

Consequently, the commercialization of scientific, technological and innovative developments in biotechnology is characterized by problems related to the whole industry. Also forms and methods of commercialization need to be chosen carefully because not all of them could be used in this industry. National problems can be explained y by the inconsistency of the state's development with the current level of innovation in the world. In particular, this concerns the imperfection of legislation in the field of protection of intellectual property (property and patent law, full and partial transfer of ownership rights to innovative developments); unfavorable investment climate in the country; insufficient funding (on the state side - limited public investment and insufficient budget financing) and inefficient public-private partnership. The industry problems include: underdeveloped infrastructure (insignificant number of technology parks, innovative incubators and science parks); low quality of information support process; insufficient financing by private investors and lack of development of the institute of venture financing and stock market. From the entrepreneurial side there is lack of resources, low innovation activity of enterprises and low level of motivation for implementation of relevant developments; outdated material and technical base. Specific industry issues include the need for a detailed and specialized approach to the registration of biological and biotechnological products, which excludes the automatic transfer of simplified requirements for chemically synthesized products.

The practical value of the results obtained is the ability to avoid sectoral problems by biotech enterprises.

Further research in this area should be devoted to the development of measures to address national problems by developing recommendations for improving of legislation.

References:

[1] Business (2016), “Commercialization is an important aspect of the economic development of the leading countries of the world” available at: http://faqukr.ru/biznes/101291-komercializacija-ce-vazhlivij-aspekt-ekonomichnogo.html (Accessed 4 Sep 2016)

[2] Drucker, P. (2007), *Business and Innovation*, Williams, Moscow, Russia.

[3] Schumpeter, J. (1935), *The Theory of Economic. Development: An Inquiry into Profits, Capital, Credit, Interest and the Business Cycle: Introduction*, Librairie Dalloz Paris, France.

[4] Romanovsky, O.O. (2012), *Fenomen pidpryiemnytstva v universytetakh svitu: monohrafiia* [The phenomenon of entrepreneurship at world universities: monograph], Nova Kniga, Vinnytsia, Ukraine.
[5] *Gorbulin, V.* (2014), "The Statistics of the Commercialization Process", *Dzerkalo Tyzhnya*, [Online], available at: https://dt.ua/ (Accessed 4 Aug 2014).
[6] Muhhopad, V.I. (2010), *Kommercializacija intellektual'noj sobstvennosti* [Commercialization of Intellectual Property], Magistr, Moscow, Russia.
[7] Shuba, I.V. (2014), "Analysis of the forms of commercialization of intellectual property objects", *Bulletin of the NTU "KhPI"*, vol. 23 (1066), pp.150-156.
[8] Polyakova, E.N. (2016), "Problems and directions of commercialization of scientific developments", *Bulletin of the Economy of Transport and Industry*, vol. 54, pp. 338-344.
[9] Olefirenko, O.M. (2016), "Commercialization of innovations in Ukraine: preconditions and national realities*", Economy and society. Bulletin of the Mukachevo State University*, vol. 6, pp. 197-202.
[10] Stanislavik, O.V. and Kovtunenko, K.V. (2011), *"*Commercializing the Results of Innovation Activity*", Odessa Polytechnic University*, vol. 2 (36), pp. 301-306.
[11] Fedulova, L.I. and Fedulova, K.I. (2012), "Formation of an Innovative Biotechnology System: Experience of Foreign Countries, Problems of Ukraine", *Science and Innovation*, vol. 8 (4), pp.51-66.
[12] Nesterchuk, M. Baula, O. Gamazin, Yu., Doroshuk, L. and Matveev, O. (2013), "Features of biological / biotechnological products and biosimilars: methodical recommendations", State Expert Center of the Ministry of Health, available at: http://www.dec.gov.ua/site/file_uploads/en/biosimilars/3.pdf (Accessed 25 January 2014).
[13] Crommelin, D. Storm, G. Crommelin, DJ. and Verrijk, R. (2003), *Shifting paradigms: biopharmaceuticals versus low molecular weight drugs*, Int J Pharm, Amsterdam, Netherlands.
[14] Tulchinska, S. (2009), *Intelektual'no-innovatsijna modernizatsiia ekonomiky Ukrainy: teoretyko-metodolohichni aspekty: Monohrafiia* [Intellectual and Innovative modernization of the Ukrainian Economy: Theoretical and Methodological Aspects: Monograph], NTUU "KPI", Kyiv, Ukraine.