

## NAUKI FARMACEUTYCZNE: EDUKACJA, EKONOMIKA I ZARZĄDZANIE

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### COMPARATIVE ANALYSIS OF INTELLECTUAL RESOURCES COMMERCIALIZATION MODELS IN UNIVERSITIES AND RESEARCH INSTITUTES OF MEDICAL AND PHARMACEUTICAL PROFILE IN UKRAINE AND ABROAD

### ПОРІВНЯЛЬНИЙ АНАЛІЗ МОДЕЛЕЙ КОМЕРЦІАЛІЗАЦІЇ ІНТЕЛЕКТУАЛЬНИХ РЕСУРСІВ У ВНЗ І НАУКОВО-ДОСЛІДНИХ ІНСТИТУТАХ МЕДИЧНОГО ТА ФАРМАЦЕВТИЧНОГО ПРОФІЛЮ В УКРАЇНІ ТА ЗА КОРДОНОМ

**Litvinova E.V., Posylkina O.V.** Comparative analysis of intellectual resources commercialization models in universities and research institutes of medical and pharmaceutical profile

It has demonstrated that an important condition for the intellectual resources commercialization of Ukrainian universities is the creation of biopharmaceutical clusters on public-private partnership. It has estimated the most significant factors relating with process of intellectual property commercialization in Ukrainian pharmacy. It has analyzed advanced prolonged strategies of patent protection intellectual property. It has offered improved intellectual property commercialization model in pharmacy.

**Key words:** intellectual resources commercialization model, innovative drug, university and research institute.

**Problem statement.** Ukrainiane current government policy focuses on the innovative development of national economy. Priorities of innovative economy include the development of pharmaceutical industry, namely the creation and production of new efficient, high-quality and safe drugs. In turn, the innovation management in pharmacy provides systematic drug portfolio rotation, formation of intellectual property base and monitoring of intellectual property legislation compliance in pharmaceutical market.

Sources of fundamental knowledge, creating the methodological basis of new original drugs and processes are universities and research institutes of medical and pharmaceutical profile. This knowledge will determine the competitiveness of universities and research institutes, pharmaceutical companies and the country as a whole. However, it is essential to create appropriate conditions and management mechanisms that would bring results of university and academic research to the mass use and commercial application [1].

**Background.** The problems of innovative development and intellectual capital management are examined by T. Stewart, L. Edvinsson, E. Brooking, Schumpeter et al. Specific aspects of the organization and management of innovation processes in the pharmacy are considered by Chernykh V.P., Hroshovyi T.A., Mnushko Z.N., Nemchenko A.S., Ponomarenko M.S., Posylkina O.V., Piven E.P., Slobodyanyuk N.N., Tolochko V.M., Chumak V.T., Timanyuk V.N., Derens'ka J.N., Kostyuk G.V. et al. [2].

**Formulation of parts of the common problem, which have not been resolved before.** Despite the fairly large number of scientific publications relating intellectual resources management, there is fragmentation and lack investigation of interests and needs of intellectual potential holders in pharmacy. In Ukraine, universities and research institutes of medical and pharmaceutical profile have formed portfolio of intellectual property, but it has not developed commercialization mechanisms of patents. The above can not

allow effectively use the innovation potential of research institutions, updating equipment of laboratories, actively participate in international conferences and congresses, organize foreign training staff, investing in new innovations.

**Aims.** The aim is to analyze and systematize methodological approaches to the intellectual resources commercialization in universities and research institutes of medical and pharmaceutical profile in Ukraine and abroad.

Studies were conducted using a database on the Internet: the Food and drug administration, European Medicines Agency, State enterprise "The State Expert Center" of the Ministry of Health of Ukraine, weekly "Pharmacy", Ukrainian patent office, scientometric databases. It has used retrospective, logical, systematic and analytical methods.

**Results and discussion.** Traditional social role of universities and institutions is to receive, accumulation and transfer knowledge to society when selecting areas and topics of research are independent of market conditions. However, the difficult economic situation in Ukraine, a significant reduction in funding for science and universities, real competition between them, formulate problems for universities and research institutes of active search and more use of additional internal reserves for innovation activation [3].

Competitiveness of any university, institute of medical and pharmaceutical profile in a market economy is determined by its ability not only to meet the public need for training and retraining of specialists, but also the ability in a competitive environment to create, to legal protection and implement intellectual property, which is adequacy for domestic and global pharmaceutical markets requirements.

Main patents of universities and research institutes of medical and pharmaceutical profile, first of all, are innovations in the field of new active pharmaceutical ingredients (API), finished dosage forms and technologies. The main

factor in the success of innovation organizations in the market is constant innovation. Therefore, universities and academic institutions of medical and pharmaceutical profile should have a "portfolio" of several innovative projects relating the development of original drugs, which must be continuously replenished. The presence of such "portfolio" is not the only factor in improving the competitiveness of innovative organizations, but also by its survival in the market environment.

The most complete realization of intellectual resources commercialization model of medical research institutions observes in the United States. The National Institutes of Health operates under the United States Department of Health and Human Services as national agency responsible for biomedical and health-related research. The structure of the National Institutes of Health includes 27 institutes and centers, each of which has its own research program, often focused on the problems of certain disease or a certain group of nosology. The National Institutes of Health is developing a work program according to the needs of modern innovation and growing trend towards conducting interdisciplinary research [4].

Essential condition of National Institutes of Health research projects implementation is the patenting of R&D results. It has created National Institutes of Health innovative information database of R&D results on the Internet for the purposes of generating and implementing innovative potential. Researchers at the National Institutes of Health each year give hundreds of new inventions and patent applications in this database.

Patent analysis has found that Ukrainian pharmacy has the experience of technology transfer, but license fees of domestic inventors is significantly lower compared with foreign scientists.

As has been demonstrated globally, creation of favorable conditions for attracting investment resources for development of domestic innovative drugs is possible only in conditions of public-private partnership which

is aimed at reviving the pharmaceutical, medical and biotech industry. It ultimately will significantly improve the situation with the Ukrainian public drug supply by national innovative drugs. Implementation mechanisms of public-private partnership involves the direct participation of the state in the development of regional infrastructure through direct budget financing, creation and use of extrabudgetary funds and assets, issuance of loans; establishing incentives to manufacturers producing domestic drugs; a variety legal and advisory support to entrepreneurs who involve in the development of the pharmaceutical sector and provide national “drug safety”.

The best partnership of the state, science, education and business implements in cluster innovation organizations. Biopharmaceutical cluster is a group of geographically localized interconnected companies, developers of innovative medicines, pharmaceutical manufacturing companies; suppliers of equipment, components, specialized services; infrastructure objects: research institutes, universities, business incubators and other organizations that complement each other and enhance the competitive advantages of individual companies and the cluster as a whole. The distinguishing characteristic of effective innovation clusters is innovation production. Cluster development policy of the pharmaceutical industry work well in practice abroad, this trend is emerging in Ukraine [5].

The formation of pharmaceutical cluster is a real mechanism to overcome organizational and financial barriers in the implementation and commercialization of innovative projects relating with the development and production of innovative drugs. Creation and development of pharmaceutical clusters in Ukraine will be able to compensate for the lack of budget investments that guided the development of the pharmaceutical industry in Ukraine and facilitate technology transfer, making close relationship between phases: development and industrial production of drugs.

Take into account the general laws of intellectual property commercialization and features of innovative drugs, the authors have worked out the risks faced by the subjects of the pharmaceutical market in intellectual property commercialization. It has been developed questionnaire for determine this risks. As experts have involved heads and specialists of university academic departments, research institutes, pharmaceutical companies and others. Over 150 professionals have took part in expert survey. Distribution by weighted average rank for intellectual property commercialization risks in pharmacy has illustrated in Figure 1.

Thus, according to experts, the risk of **employer breach of confidentiality**; the risk of violation of intellectual property rights and equitable distribution of income between the employee and the employer, the employee and the customer (company or government); the risk of infringement of third-party rights; the risk of loss of patent protection are the most significant factors relating with process of intellectual property commercialization in Ukrainian pharmacy.

The risk of **employer breach of confidentiality** is the most threatening for pharmaceutical market. For example, the interests of scientific researchers (Ph.D. defense) demand of immediate publication of results, but commercial interests involve temporary secrecy of the results for following patenting.

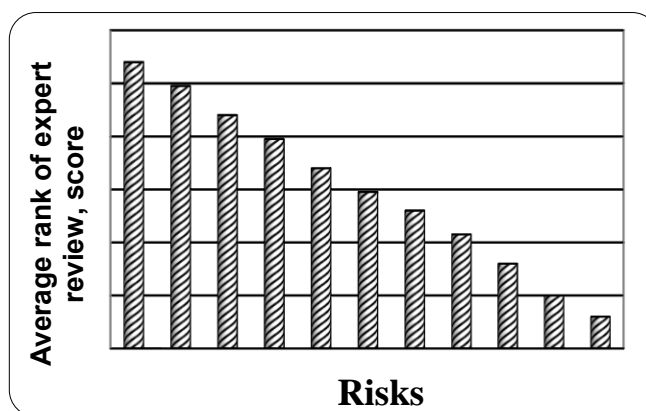


Figure 1. Histogram of distribution by weighted average rank for intellectual property commercialization risks in pharmacy

X4 – the risk of **employer breach of confidentiality** (disclosure at conferences, exhibitions, publications, theses, articles);

X8 – the risk of violation of intellectual property rights and equitable distribution of income between the employee and the employer;

X7 – the risk of violation of intellectual property rights and equitable distribution of income between the employee and the customer (company or government);

X3 - the risk of infringement of third-party rights;

X5 - the risk of loss of patent protection;

X2 - the risk of non-compliance with confidentiality between the contractor and the customer;

X6 - the risk of research failure;

X1 - the risk of low motivation researchers;

X11 - the risk of violations of intellectual property rights and equitable distribution of income between composite authors;

X10 - the risk of incorrect detection of intellectual property object;

X9 - the risk of wrong choice of patent protection.

Separates group include risks of violation of intellectual property rights and income distribution, where the main participants are: the researcher as an employee of the university; the university as an employer; the university as a contractor; a customer - the state, a customer - a pharmaceutical company.

It should be noted that in the 80 years the US and Britain have made maximal effort to resolve conflicts related to division of intellectual property rights between the state and universities, who performed research out of public funds. The Bayh-Dole Act allows for the transfer of exclusive control over many government funded inventions to universities and businesses operating with federal contracts for the purpose of further development and commercialization. While US law clearly defines the mechanism for the

implementation of intellectual property transfer to university, but such a mechanism is absent in Ukrainian legislation.

The distribution intellectual property rights of “contractor-customer” results of R&D is defined in Ukrainian Civil Code. Proprietary rights of intellectual property in the object created to order shall be vested jointly with the author of this object and the customer, unless otherwise established by the agreement.

Studies have also found that the most significant intellectual property commercialization risks in pharmacy is related loss of patent protection. The pharmaceutical industry is facing serious financial problems at the end of patent protection for blockbuster. Pharmaceutical companies use a number of strategies to increase the term of protection of APIs, prolonging the stage of commercialization of pharmaceutical innovation for the purpose to minimize the risk of loss of patent protection on key drugs (Figure 2).

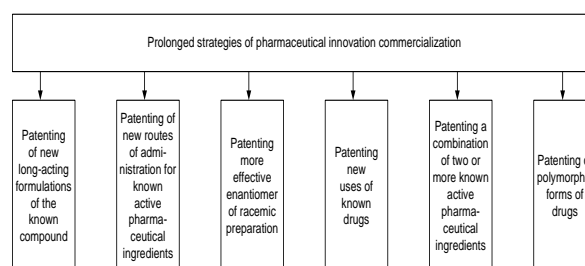


Figure 2. Prolonged strategies of pharmaceutical innovation commercialization

Thus, the commercialization of intellectual resources in universities and research institutes of medical and pharmaceutical profile has special aspects. Development and implementation of medicines is a long, costly and risky process that requires significant investment and time.



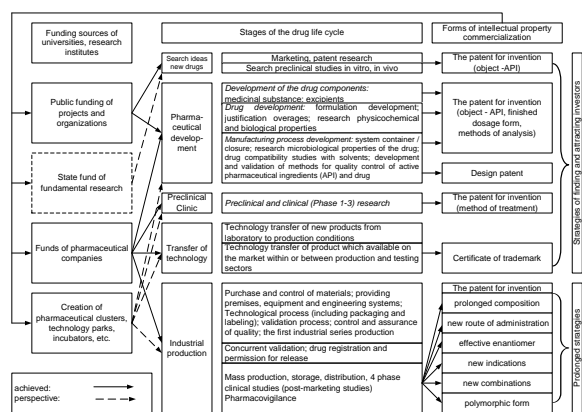


Figure 3. Intellectual property commercialization model in pharmacy (completed by source [6])

Availability of intellectual property protection system is one of the main conditions for effective innovation activity. In this regard, the authors have analyzed and systematized innovation activity experience of foreign and domestic universities and research institutes. It has offered improved intellectual property commercialization model in pharmacy (Figure. 3).

### Conclusions and prospects for further research

1. This studies indicate that intellectual resources commercialization of universities and institutes of medical and pharmaceutical profile increases their competitiveness, promotes the development of scientific and technological progress in the field of pharmacy.

2. It has established the features of intellectual resources commercialization in the system of US medical research institutions that are included the patenting of R&D results, the creation innovative information database of R&D results on the Internet, the possibility of electronic filing to conclude a license agreement on the website of the developer and others.

3. It has demonstrated that an important condition for the intellectual resources commercialization of Ukrainian universities is the creation of biopharmaceutical clusters on public-private partnership.

4. It has estimated the most significant factors relating with process of intellectual property commercialization in Ukrainian

pharmacy: the risk of **employer breach of confidentiality**; the risk of violation of intellectual property rights and equitable distribution of income between the employee and the employer, the employee and the customer (company or government); the risk of infringement of third-party rights; the risk of loss of patent protection.

5. It has analyzed advanced prolonged strategies of patent protection intellectual property, which in turn are essential for the creation of effective mechanisms for their commercialization.

6. It has offered improved intellectual property commercialization model in pharmacy, which significantly enhances the ability of universities and research institutes to accumulate the necessary financial resources for innovation.

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