CURRENT TRENDS IN PATENTING OF NANOPHARMACEUTICAL INNOVATIONS

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Introduction: in today's economy, innovation plays a significant role: create competitive products that have a high-tech and innovation; lead to lower production costs, to an influx of investment, to improve the image of the manufacturer's new products and the opening of new markets, including foreign ones.

There are following promising research areas of nanopharmaceutical innovation: nanoparticles as drugs, nanoparticles as containers for targeted drug delivery to the target cells, and others.

Purpose: to analyze the current state of the patent situation, trends and developments on the application of nanotechnology in the pharmaceutical field.

Methods: studies were conducted using a database on the Internet: Ukrainian patent office, patent office of the Russian Federation, the European patent office, the US patent office, the Food and drug administration, European Medicines Agency (EMEA), State enterprise “The State Expert Center” of the Ministry of Health of Ukraine. It was used retrospectively, logical and systematic and analytical methods.

Results: it was established that significant number of nanopharmaceutical products have been registered at the global pharmaceutical market. Patent research to point to active patenting nanoparticles of pharmacologically active substances and their production technologies, medicines in the form of nanocarriers. The data indicates potential and demand nanopharmaceutical products in the global pharmaceutical market. It should be noted that nanotechnology is used in the drug development of most pharmaceutical groups. Thus, among the analyzed patents and applications there are drugs for treatment alimentary tract and metabolism, including anti-diabetic drugs; drugs affecting blood system and haemopoiesis, cardiovascular system, including lipid lowering agents; dermatological, antimicrobial, antineoplastic

and immunomodulating agents; drugs affecting the musculoskeletal system. These drugs help to more effective therapy, prolonging the action, prolonged circulation in the blood, targeted delivery to the target organ, safety.

Medicinal products based on nanotechnology are expensive drugs. However, these costs are justified in medical practice, especially in the treatment of diseases such as tuberculosis, AIDS, cancers, prolonging the life of patients and improving their quality of life. Thus, the benefits of nanoliposome anticancer drugs include the possibility of targeting chemotherapeutic substances in the tumor and foci of inflammation, as well as reducing the toxicity of drugs, to increase their safety.

It should be noted major foreign pharmaceutical corporations (Pfizer, GlaxoSmithkline, Merck & Co, AstraZeneca, Squibb Bristol Myers, Hoffmann La Roche etc) have patented innovations in nanotechnology.

Data classification has revealed that, despite the opportunities of the introduction of pharmaceutical innovation, in modern science there is a problem of risk assessment of nanoparticles in relation to man and the environment. There is some difficulty in identifying the degree of toxicity of nanodrugs. A significant problem is also failure detection methods and quantifying nanoparticles in the environment, food. There is uncertainty about the risks of many products nanomedicine, concerns about the adequacy of regulatory pharmacovigilance, uncertainty about the potential health risks.

Experience of pharmaceutical companies have engaged in the commercialization of nanotechnology shows that along the way there are also many obstacles: a long period of launch to market, high technology risks in uncertain benefits at the start of work, the high cost of development and deployment of nanotechnology, the complexity of scaling of laboratory results, the complexity of the legal protection and intellectual property protection (detection of an infringement of the nanotechnology requires expensive research methods). In addition, for applied research is necessary to involve specialists from different disciplines and possess knowledge at different levels of scale (nano, micro and macro). It should be noted the

international experience on the implementation of collaboration funded by various sources, thereby reducing the risk to the individual investor.

The complexity of the legal protection of intellectual property leads to the use of the following recommendations: identifying the maximum number of direct effects and additional technical features of nano-objects due to the diversity of their properties; combined “nano features” with features of traditional technology to produce new positive qualities due to their interaction; concealment of know-how by bringing extended range operation of processes. In some cases, especially when there are doubts about the grant of a patent, it is advisable to postpone substantive prosecution. Because scientists can be opened new properties of nano-objects: nanoemulsions, fullerenes, nanotubes, etc. and this will increase the likelihood of acquisition of patent.

Conclusion: thus, the studies indicate the prospects and feasibility of using nanotechnology in the field of pharmacy in the development of drugs in the form of nanoparticles, as well as the nanocontainers with high pharmacological activity, bioavailability and safety. In developing nanopreparations there are certain difficulties associated with the duration of the period of launch to market, technological risks, problems in detecting toxicity, and methods for the quantitative determination of insufficiency of nanoparticles in the environment and others. However, there is no doubt that the success of the creation, production and use such drugs is the presence of an effective system of patent protection.