

LEGAL PROTECTION OF INVENTIONS WITHIN MEDICAL PRACTICE IN UKRAINE

OCHRONA PRAWNA WYNAŁAZKÓW W MEDYCYNIE NA UKRAINIE

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REVIEW ARTICLE

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Abstract

Introduction: There is a large number of patents registered in the field of medical practice in Ukraine. Despite this, the peculiarities of the legal protection of inventions within medical practice have not been researched in the modern legal doctrine of intellectual property.

The aim of this article is theoretical and practical study of the legal protection of medical inventions in Ukraine based on the analysis of Ukrainian patent law, issued patents for inventions applied within medical practice, as well as data from the State Expert Center of the Ministry of Health of Ukraine.

Materials and methods: The authors of the article have used methods of analysis and synthesis, as well as comparative and legal method. The analysis and further use of data from the State Expert Center of the Ministry of Health of Ukraine contributed to the definition of the problems of this publication, as well as the formulation of the authors' vision of the features of inventions within medical practice.

Review: Inventions within medical practice are the result of human intellectual activity in the field of medicine. The authors have offered to refer inventions within medical practice to a group of inventions with a possible risk. The risks of inventions within medical practice are divided into those that have a risk for people undergoing clinical trials and manufacturers who try to use these inventions.

Conclusions: The authors have grounded the expediency of supplementing the patent procedure with regard to inventions that can be applied within medical practice, with the rule of obligatory provision of documents on conducting clinical trials to the materials of the application for a patent on the invention, in cases of restrictions of the rights of a patent holder of medical and pharmaceutical inventions, by the provisions that would define the concepts and types of biotechnological inventions.

Keywords: inventions within medical practice, legal protection of inventions, a patent and an invention, clinical trials, risks of inventions

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Introduction

Chinese scholar, Jiang-ying He, in November 2018 made a statement on the birth of the first genetically “reformed” children in the world, which immediately caused international protest by geneticists [1]. This example proves that the problem of protecting inventions within medical practice is relevant, as it requires the development of new ethical standards and proper legal regulation. Inventions within medical practice can affect both the health of a person, and his life, which according to the Art. 3 of the Constitution of Ukraine is recognized as the highest social value in the state [2]. Such a constitutional approach to protecting a person requires a detailed elaboration of all actions that can affect human life, in particular the invention activities within medical practice.

Patentable inventions can be made during normal medical practice. For example, the development of new biocompatible polymers, the improvement of dental materials, new or modified catheters, new laboratory diagnostic tests and advanced medical devices [3]. But most of the inventions applied within medical practice are the result of many years research by individual scholars, groups of physicians or specialized medical research institutes. Despite the significant number of patents registered in Ukraine in the field of medical practice, the modern legal doctrine of intellectual property practically does not study the terms of legal protection of inventions within medical practice. Such an approach does not make it possible to determine the types of inventions within medical practice, the conditions for granting them legal protection, in particular taking into account the correlation of interests of a patent holder and patients, the ethics of medical invention activities. This problem for Ukraine is relevant because it has a practical and theoretical basis. Modern Ukrainian legislation is aimed at harmonization with European law, in particular in the field of intellectual property, and scientific research in this area began to correlate with the achievements of European, American and other leading foreign scholars.

The common problem that is researched by intellectual property professionals in Ukraine, the EU, and the United States is inventions within medical practice, since the requirements of humanity and morals offered for these inventions should be understood in the same way. These inventions can be predominantly admitted industrially suitable only after clinical trials over a person, which leads to competition of human rights to safety, health care and the right to modern medical care, which may include experimental trials to facilitate human treatment.

The aim

The objective of this article is theoretical and practical study of the legal protection of medical inventions in Ukraine based on the analysis of Ukrainian patent law, issued patents for inventions applied within medical practice, as well as data from the State Expert Center of the Ministry of Health of Ukraine. The main task was to formulate propositions for improving the legislation of Ukraine in the field of protecting inventions within medical practice. The main task was to characterize the inventions applied in medical practice, to identify the risk of these inventions, to offer propositions for improving the Ukrainian legislation in the field of protection of inventions in medical practice.

Materials and Methods

Understanding the essence of the legal protection of inventions within medical practice was accomplished through the use of methods of analysis and synthesis that were applied to normative and legal acts, scientific publications in the field of invention activities within medical practice. The analysis and further use of data from the State Expert Center of the Ministry of Health of Ukraine contributed to the definition of the problems of this publication, as well as to the formulation of the authors' vision of the features of inventions within medical practice. The application of the comparative and legal method made it possible to formulate propositions aimed at bringing Ukrainian legislation in line with European standards in the field of inventions that can be applied in medicine.

The article of Zoran Miladinovis, Siniša Varga, Marija Radojkovi, "Patent law protection inventions in medicine and pharmaceutical industry" [4] is focused on studying inventions in the medical and pharmaceutical field. Scholars divide inventions within medical practice on the following groups: substances or compositions for diagnostic, surgical and other purposes; inventions associated with surgical, therapeutic and diagnostic methods; product inventions (for example, medicaments and medicines). They determine that inventions in the field of medicine are divided into medical products (medical equipment, diagnostic methods) and pharmaceuticals (medicines). This is a broad approach to understanding the inventions within medical practice, covering both inventions in the field of medicine and pharmacy.

The work "Personalized Medicine and Patent Law" of Zeynep Timocin Cantekin, addresses the scientific issue of personalized medicine that is associated with such medical inventions as an isolated DNA molecule, and the method for comparing the sequence of samples taken from a patient's DNA to the declared standard sequence. These are inventions that can be patented as inventions of biotechnology [5]. This research makes it possible to

refer biotechnological inventions to inventions that are used within medical practice. The inclusion of such inventions to patentable leads to the need to apply ethical norms that have the priority over legal ones. This is due to the fact that the creation of any invention, in particular in the field of medicine, involves the experiments that are always interfering with the human right to life and the protection of his health. Therefore, the authors of this article relied on the research outlined in the scientific work of Benjamin Mason Meier entitled “International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent” [6].

We note that the problem of the protection of medical inventions in the Ukrainian legal science was not almost considered. Some scholars (for example, O. M. Slobodian) only referred to the issues of protecting inventions of biotechnology [7].

Review and discussion

Inventions within medical practice are the result of human intellectual activity in the field of medicine, which has novelty, inventive level, industrial suitability and is protected by a patent. Types of inventions within medical practice are: methods of human treatment; devices for the treatment and diagnosis of a person; medicines; strains of microorganisms used to diagnose a person’s disease or his treatment; biotechnological inventions. These inventions are divided into two groups: medical and pharmaceutical.

The peculiarity of medical inventions is in their risks, which can be manifested in human experiments during clinical trials and risks for future production. The process of their invention activities is obligatory linked to clinical trials. Passing successful experiments on animals necessarily passes to the stage of trials over humans. Most inventions within medical practice have risks for the application in industry, and therefore, before being passed on to commercial organizations, medical tests should be conducted to minimize the technical risks associated with the biology and peculiarities of a human body [8]. The presence of a risk in medical inventions distinguishes them from other inventions. The risks of inventions within medical practice should be divided into risks for people undergoing clinical trials and manufacturers trying to use such inventions. Therefore, these inventions should be considered to a group of inventions with a possible risk.

Each of these inventions must undergo clinical trials that are necessary to achieve the benefit for a patient [9]. All clinical trials in Ukraine are conducted in accordance with international ethical principles to ensure the protection of the rights, safety and well-being of those under study. Clinical trials can only be conducted, if the expected benefit justifies the risk, as well as with the informed consent of a patient to conduct a clinical trial [10]. Ukraine is an open country for carrying out clinical trials of medical inventions and medicines.

One should pay attention to such a specific feature of inventions that can be applied in medical practice, as their compliance with ethical standards, which is that their creation can not violate the natural development of a man. In the case of the violation of the norms of morals, humanism while creating a medical invention by an inventor, it will not obtain patent and legal protection.

Medical practice in Ukraine is considered as a professional activity of medical and pharmaceutical employees who carry it out as professionals and specialists in the field of health care [11]. Therefore, inventions within medical practice are divided into two groups: medical inventions (used in medicine) and pharmaceutical inventions (related to the invention of medicines). Medical inventions include methods for treating humans; devices for the treatment and diagnosis of a person; strains of microorganisms used to diagnose a person's disease or his treatment; biotechnological inventions. Pharmaceutical inventions include medicinal drugs. Inventions within medical practice obligatory undergo clinical trials. Medical and biological experiments on humans are allowed in Ukraine. Such a conclusion follows from the fact that according to the Art. 45 of the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care", the use of medical and biological experiments on people in Ukraine is allowed with a socially beneficial purpose, in case if they are scientifically sound, the benefits of possible success in the risk of causing grave consequences for health or life, publicity of experiments' application, full awareness and free consent of an adult capable individual, which is subject to experiment, with regard to the requirements of its application, and also in terms of preserving medical secrecy in necessary cases. It is forbidden to conduct a research experiment on patients, prisoners or prisoners of war, as well as a therapeutic experiment on people, whose diseases do not have a direct connection with the purpose of an experiment [12]. Information on clinical trials of drugs obtained from the State Expert Center of the Ministry of Health of Ukraine indicates on the number of such experiments. While researching this information, the authors of this article selected the direction "Dermatology" and divided the data depending on the manufacturer of medicinal products (national or international company). In total, experiments related to 46 medicinal products, including 43 products from national producers and 3 from international ones. 27 national and 16 international sponsors were identified within national applicants for the clinical trial. In regard to the correlation of the number of experiments in Ukraine and in the world, we provide the following sample data: 1) 100% international investment company "Quintiles Ukraine", as of June 30, 2017, plans to conduct 190 experiments in Ukraine out of the planned 240 experiments in the world; 2) the Swiss company AbbVie Biopharmaceutical Sciences GmbH as of August 14, 2017 planned 225 experiments in Ukraine, and 1640 in the world [13]. The given data indicates that clinical trials in Ukraine are conducted with respect to national and international drug manufacturers. Therefore, Ukraine is included in the system of world clinical experiments. In this case, clinical experiments are not part of the system of legal protection of these inventions.

Clinical experiments in Ukrainian law fall into the sphere of regulation of medical law, and the legal protection of inventions within medical practice is regulated by the norms of intellectual property. This state indicates the imperfection of modern Ukrainian intellectual property legislation. The Law of Ukraine "On Protection of the Rights to Inventions and Utility Models" [14] does not specify the features of the protection and patent procedure of these inventions, and does not establish any restrictions on the verification of their industrial suitability. Herewith, there is a precedent, when the features of the patent procedure for strains of

microorganisms were determined. It is about the Instruction on the procedure for the storage of microorganisms' strains in Ukraine for the purpose of conducting a patent procedure, which indicates that the storage of microorganisms strains must precede the filing of an application for an invention [15]. Therefore, it is necessary to establish the peculiarities of the patent procedure concerning inventions that can be applied within medical practice. These may be the rules on the obligation to add documents on conducting clinical trials to the materials of the application for a patent for an invention. Providing documents for carrying out clinical trials allows both to establish the industrial suitability of such an invention, and additional guarantees for the future manufacturer of such an invention, as this, for example, will reduce production risks.

While considering inventions within medical practice it is necessary to determine their risks. The risk is a justified necessity, grounded by the need to attract hazardous objects in a certain area of activity [16]. The use of inventions within medical practice is always associated with the risk of unknowing consequences for the human body, but this risk is justified by the need for the development of medicine in the.

The risks to humans in the inventions applied within medical practice are related to the fact that these inventions include biotechnological inventions that, for example, are related to a human biological material. As it was previously mentioned Chinese scholar, Jiang-ying He, stated on the possibility of modifying human DNA [1]. Can such experiments that have been actually introduced into public life, affect the future of mankind? It is probably difficult to provide a clear answer nowadays, because there is a risk that people along with positive changes will get a negative mutation. To prevent this, it is necessary to introduce a single standard for the legal protection of biotechnological inventions. Thus, one of the problematic issues of the legal protection of medical inventions in Ukraine is the protection of biotechnological inventions. There is no concept of this invention in the Ukrainian patent law, and therefore researchers of intellectual property use the norms of the Directive of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions. According to the Art. 3 of this Directive, "inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature" [20]. The absence of the norms in the Ukrainian legislation that would regulate the relations in the field of biotechnological inventions may have negative consequences (for example, the abuse or use of such a state in someone's interests). However we believe that the restrictive mechanism today is the provisions of Part 1 of the Art. 6 of the Law of Ukraine "On the Protection of the Rights to Inventions and Utility Models", according to which the legal protection is provided to an invention that does not contradict the public order, the principles of humanity and morals and corresponds to the requirements of patentability [2]. The problem of this norm is that it has not received a clear interpretation and a mechanism for its implementation at the subordinate level. Just the notion of public morality, which is the system of ethical norms, rules of conduct that have been

developed in society on the basis of traditional spiritual and cultural values, ideas about goodness, honor, dignity, public duty, conscience, justice (paragraph 11 of the Art. 1 of the Law of Ukraine “On the Protection of Public Morality”) is legally consolidated [21]. Therefore, the lack of a correlation of ethical and legal norms in the invention activities and application of biotechnological inventions in Ukraine is a legal gap.

The peculiarities of inventions within medical practice are not taken into account in the legal protection of these inventions, in particular, it is not defined in the patent procedure and restrictions of patent rights in the interests of society. The patent and legal protection of inventions involves the exclusive rights of a patent holder to the invention. It is a particular problem for inventions within medical practice, since a patent may be a limitation for the treatment of many people. For example, the state spends more than 50% of all funds allocated for purchasing antiretroviral drugs for the treatment of patients with HIV / AIDS in Ukraine, because of patenting a vital drug for the treatment of HIV / AIDS (a drug lopinavir / ritonavir). The indicated drug is protected in Ukraine by two secondary patents (on the derivative substance and method of treatment), which created an artificial monopoly in Ukraine until 2026 [22]. This example was the first in the history of patent law in Ukraine, which revealed a lack of a regulated balance of interests between patent holders of the invention that can be applied in medical practice, and society. Society while determining the exclusivity of the rights of patent holders has the right to reserve cases of restricting the rights of patent holders, if the use of the patented object is necessary for society’s life-sustaining activity. In this case, private interests depart from broader public interests. In order private interests of patent holders are not violated by the interference with a public element, in particular in the form of abuse by public authorities, the patent law should clearly identify the cases of restricting the rights of patent holders of medical and pharmaceutical inventions.

Conclusions

Based on the conducted research it has been established that inventions within medical practice are the result of human intellectual activity in the field of medicine, which has novelty, inventive level, industrial suitability and is protected by a patent. These inventions are related to inventions having a risk. The risks of inventions within medical practice should be divided into risks for people going through clinical trials and manufacturers who try to use these inventions. The presence of risks in these inventions distinguishes them from other inventions and indicates on their specific features.

The legal protection of inventions in the medical practice of Ukraine consists of a complex of the norms of medical law and intellectual property right. These norms do not have a relationship that negatively may affect the level of their industrial suitability and the risks while using these inventions. This state of Ukrainian legislation indicates the expediency of further scientific research of the topic concerning legal protection of inventions within medical practice.

It is appropriate in the patent law of Ukraine: to establish the peculiarities of the patent procedure concerning inventions that can be applied within medical practice (for example, the rule on the obligation to add documents on conducting clinical trials to the materials of the application for obtaining a patent for an

invention); to supplement the patent law of Ukraine with the provision on biotechnological inventions; to identify cases of restrictions on the rights of the patent holder of medical and pharmaceutical inventions.

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Conflict of interest:

The Authors declare no conflict of interest.

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