

# THE DIRECTIONS OF DEVELOPMENT OF LEGAL REGULATION OF PATENTING THE METHODS OF TREATMENT IN UKRAINE CONSIDERING THE EUROPEAN AND WORLD EXPERIENCE

## KIERUNKI ROZWOJU REGULACJI PRAWNYCH DOTYCZĄCYCH OCHRONY PATENTOWEJ METOD LECZENIA NA UKRAINIE UWZGLĘDNIAJĄC DOŚWIADCZENIA EUROPY I ŚWIATA

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### ABSTRACT

**Introduction:** the current state of patenting legal regulation of medical treatment in Ukraine and in the world is analyzed, the directions for the further development are determined. The author defines “non-industrial medical” and socio-ethical theories in the field of medical treatment patent protection. The existence of exclusively formal “monopoly” of the patent owner is noted, as well as the inapplicability of the majority of the patented achievements in this field in Ukraine.

**Aim:** the purpose of this article is to investigate the current state of patenting legal regulation of medical treatment in Ukraine and in the world, to analyze the limitation of patent protection basic conception in the medical field and to determine the tendencies and perspectives of the legal protection mechanism of further development in this field in Ukraine, considering the European and world regulation experience.

**Material and Methods:** this study is based on Ukrainian regulation acts, The European Patent Convention, The Code of Laws of the United States of America, judgments, scientific works and opinions of progressive-minded people in this sphere. Such methods as dialectical, comparative, analytic, synthetic and comprehensive are used in the article.

**Conclusion:** The experience analysis of the medical treatment patenting regulation in EU and in other countries of the world made it possible to substantiate the tendencies of development the patenting legal regulation of treatment methods mechanism, based on the needs of creation conditions for the availability of the recent treatment developments and technics for citizens, without increasing the cost of such treatment through license fees.

**KEY WORDS:** the patenting of methods of treatment, an invention in the medical field, patenting in the medical field, the socio-ethical theory, the non-industrial medicine theory

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### INTRODUCTION

Ukraine is on the way of reforming the sphere of quality management of health care. Work in this direction is important, especially given the existence of real problems in the implementation of citizens' rights to medical care. In addition, this process is further complicated by opposing approaches in legal regulation in Ukraine and the world's leading countries, the access of doctors and patients to the latest methods of therapeutic and surgical treatment and diagnostic methods applied to the patient.

It should be acknowledged that for developing countries, including Ukraine, patent policies are not just about increasing the rate of innovation, but are to be calibrated to take into account concerns of “access” to technology goods. The question of access is most significant in the context of pharmaceuticals and public health [1]. Therefore, the patent regime cannot be hermetically sealed off from other public policy concerns such as health. Indeed, one often witnesses a conflict between patent rights on the one hand, and social values, public policies and fundamental rights

on the other. The issue for most countries then is to balance out these competing and often conflicting concerns and devise a regime that would, while furthering innovation outcomes, also not erode important values such as health. [2, p. 2]

First of all, we are talking about Ukraine's belonging to the small group of countries in the world where the certain person still has the possibility to establish a monopoly for new methods and methods for the prevention, diagnosis, treatment, rehabilitation of a person through the mechanism of their patenting as inventions or utility models. In other words, the state at the level of the law establishes, as a general rule, the priority of the patent owner's property rights over the natural, inalienable human right to health protection, whose content element is the choice of methods of treatment in accordance with the recommendations of the doctor and the health care institution. The assertion of specialists is justified, that the monopolization of medical knowledge in the form of objects of intellectual property rights lays the conflict

between the interests of its owner (doctor, medical institution, research institution) and the patient, limiting the latter the freedom of choice of treatment methods guaranteed to everyone in the WHO statute, fundamentals of Ukrainian healthcare legislation, etc. [3, p. 43].

## THE AIM

The purpose of this article is to study the current state of the legal regulation of patenting of treatment methods in Ukraine and the world, to analyze the main concepts for limiting patent protection in the medical field and to determine the directions and prospects for the further development of the legal protection mechanism in this area in Ukraine, taking into account the European and world regulatory experience.

## DISCUSSION

The possibility of extending the special legal protection granted to the objects of patent law to the methods and methods of treatment is explained by the fact that the object of the invention (utility model), the legal protection to which is granted according to the Law of Ukraine "On the protection of the rights to inventions and utility models" [4] is not only the product (device, substance, etc.), but also the process (method), as well as a new application of a known product or process (Part 2, Article 6 of this Law).

International treaties and legislation of the vast majority of countries in the world recognize as obligatory conditions of patentability of the invention its compliance with three criteria: novelty, industrial applicability and inventive step. For patenting a utility model, it is sufficient to declare its compliance only with the first two of these criteria. The special restrictions or prohibitions regarding the patenting of methods and methods of treatment by the legislation of Ukraine are not provided. Consequently, in modern conditions, it becomes possible to obtain a state-protected monopoly on methods of treatment and methods for diagnosing any human diseases, such as: a cataract treatment method (patents for inventions UA 75548 C2 and UA 51723 C2) [5], a method for the complex treatment of coronary heart disease (patent for utility model UA 65289 U), a method for treating upper respiratory tract and lungs (patent for invention UA 85259 C2), a method for treating joint damage (patent for invention UA 94726 C2) and many others. Particularly accessible for obtaining such patents becomes, taking into account the narrowly specialized direction of the results protected by them, the possibility of using the majority of methods of treatment only in medical institutions, which have expensive specialized equipment, as well as the complexity of verifying the reliability of the claimed data in the description of the invention (utility model). In addition to Ukraine, a similar situation in the field of patenting the methods of treatment and diagnosis exists in the Russian Federation and other CIS countries, South Korea, Nigeria and Australia. This possibility is also allowed in the United States, but patent owners for

the treatment method in this country receive only limited protection of their intellectual rights without the possibility of applying jurisdictional protection procedures to persons who use patented developments. These states form an almost complete list of countries in the world in which patenting of methods of treatment and methods of human diagnostics is allowed.

Absolutely the opposite approach in the field of patenting of medicinal procedures is observed in all countries of the European Union, Canada, Mexico, New Zealand, Brazil, Argentina and other countries of South America, Asia, the African region and so on. In these countries patents on methods for treating humans or animals via surgery or therapy and diagnostic methods, that are used for human or animal, are not granted. This is done at the level of a law or an international treaty by imposing an outright ban on the granting of patents for these procedures (member countries of the European Patent Convention, member countries of the Regional contract African Intellectual Property Organization, etc.) or by determining in-law, judicial or enforcement practices of the authorized body of patenting a specific country treatments industrialized unsuitable scientific and technological achievements that involve make it impossible to obtain a patent on them due to a mismatch requirements of patentability (Japan, Canada, New Zealand, Venezuela, etc.).

The validity of the exclusion of treatment methods from the range of inventions to which patent protection can be granted is a subject of discussions that continue in professional medical and legal circles in many countries of the world. In support of patenting in the field of medical technologies, it is noted that the granting of exclusive rights for a limited period has a positive effect on the inventive activity of scientists and specialized agencies, taking into account the ability to receive income from the use of such technologies. The lack of legal protection in the form of patents reduces the readiness of research companies to invest in research aimed of developing methods for treating patients [6]. In addition, proponents of the concept of patenting, trying to mitigate the hard resistance of their opponents, indicate that the state can always limit the monopoly of the patent owner to "socially significant inventions" through the mechanism of compulsory licenses [7, p. 8]. In this case, the doctor has the right to use such an invention, and the author will receive appropriate compensation for this. In particular, in Ukraine such powers of the government are defined by Part 3 of Art. 30 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models", which states that in order to ensure public health, state defense, environmental safety and other public interests, the Cabinet of Ministers of Ukraine may authorize the use of a patented invention (utility model) if the patent owner (declarative patent) unreasonably refuses to issue a license to use the invention (utility model).

In support of the prohibition against the patenting of methods of treatment, some arguments are adduced, but they have formed the basis for the emergence of two opposing in the sense, but similar in the direction theories:

non-industrial medicine theory and socio-ethical theory [8, p. 131]. According to the first theory, it is noted that medical activities cannot be regarded as industrial, and therefore all inventions in this sphere cannot be considered industrially suitable. At the same time, supporters of this specify that only those methods of treatment that require medical knowledge and special skills of a doctor are not eligible for recognition and patent protection. In all other cases, we are talking about industrially useful inventions. In support of this theory, it is argued that in the “true” technical process, whether it is a mode of production or a way of using the device, the correct initial data leads to a reproducible result. In the medical field, the expected result is not always obtained, since the body of a person or an animal has its own laws and special reactions to medical intervention [7, p. 14].

Socio-ethical theory, as opposed to the first one, does not exclude the methods of treating a person from among patentable ones depending on their industrial applicability. Proponents of this theory note the existence of reasons of a special kind (mainly socio-ethical nature), which make it impossible to establish a patent monopoly on these methods. Some of these reasons are described below.

First, doctors need to follow the rules of information exchange related to the application of the latest achievements in the field of professional activity. This rule is set at the level of ethical principles of the doctor. In particular, section 2 of the Principles of Medical Ethics of the American Medical Association (1957) [9] establishes that “doctors should constantly strive to improve medical knowledge and skills, and should make available to their patients and colleagues the benefits of their professional achievements.” The Ethical Code of the doctor of Ukraine contains a similar rule: “A doctor must constantly improve their skills, be informed about the latest achievements in the field of professional activity. ... On the results of their research after the registration of the copyright to the discovery, invention, etc. the doctor must inform his colleagues ...” (clauses 7.1, 7.3, 7.6 of the Code) [10].

In other words, the monopolization of new knowledge in the field of medical technology, which may be a consequence of the requirements of the patent system, contradicts the principles of medical ethics and is unacceptable.

In addition, the patenting of treatment methods can significantly limit the permissibility of advertising the services of organizations in the field of health protection, based on the need to obtain prior permission from the owner of the patent for the use of the protected object in public announcement. [11]

Secondly, it is necessary to prevent the increase of healthcare costs associated with the payment of royalties to patent holders, because this create barriers to access the implementation of citizens’ right to healthcare.

If medical methods have been patented, then their usage will require the signing of a license agreement. Therefore, doctors will have to charge patients a higher price to pay a license fee. This will inevitably lead to an increase in healthcare costs and will impede public access to health care [8, p. 136].

Thirdly, the compulsory observance of patients’ rights to confidentiality, since proof of the usage of the patented method will inevitably lead to disclosure of the content of the care that was provided to the patient. Moreover, this, in turn, violates the patient’s right to a secret about the state of his health.

Fourthly, this is a protection from limiting the scope of the autonomy of the doctor because of the attempt to avoid the usage of patented methods of treatment or the selection of those of them for which it is necessary to pay less. As the researchers note, autonomy is the control over one’s own decision, this is freedom from coercion in making a decision to act, which is available on the following grounds: 1) the person acts intentionally; 2) with understanding, and 3) without a controlling influence that can affect the voluntary nature of the person’s actions [12, p. 58-59].

Fifthly, it is necessary to exclude conditions conducive to the realization of the desire of physicians to obtain additional benefits, which can manifest themselves in imposing on the patient methods of treatment for the use of which the doctor can receive a royalty payment. In other words, it is about the possibility of the internal conflict of a doctor: on the one hand, a person is guided by the moral and ethical norms proclaimed in the Oath of the World Medical Association doctor, “the health of my patient will be my first consideration”, and the vow of a doctor Ukraine about disinterestedness, and on the other hand, as the owner of the patent, the person will try to realize its powers to receive income for the use of his own developments in the medical field.

The factors cited in favor of the refusal to grant patent protection to treatment methods, methods for diagnosing the human body in Ukraine are of the same importance as in other countries, at the level of the law, the provisions of socio-ethical, and non-industrial medical theories have been put into effect. In modern conditions, the state does not receive significant positive results from granting patent protection to medicinal procedures, since the absence of such protection in most countries makes it unattractive for foreign investors from an economic point of view, and in our country there are no conditions for obtaining significant revenues from their commercialization. At the same time, the negative impact of the formally existing monopoly on patented methods of treatment is offset by a relatively low share of paid medical services in their market, the lack of effective mechanisms for ensuring the rights of owners of such patents, the low level of legal culture of these individuals and the state’s significant restriction of the autonomy of a doctor in relationship with the patient in determining the mode of treatment. In this regard, specialists in this field are proposing to reduce the level of patent protection in the medical field. [13]

Considering the foregoing, it is necessary to identify several possible ways of developing legal regulation in the field of patenting the methods of treatment in Ukraine. The first is the abandonment of the existing system of patenting in the field of treatment technologies with the formal “monopoly” of the patent owner and patented achievements in this field, which in many cases are also formal. This situation exists, with the statutory possibility of obtaining patent protection



for technical achievements without conducting a qualification examination, i.e. examination of the merits of the invention. These are declarative patents for inventions and utility models issued based on the results of a formal examination, without exploring the novelty and industrial applicability of the claimed decision, under the applicant's liability.

The second is the introduction of the European model of patenting in Ukraine, with the exception of the possibility of obtaining a patent for "methods of treating people or animals by surgery or therapy, and diagnostic methods that are used for humans or animals" (Article 53 of the European Patent Convention 05.10.1973, revised by the act of 29.11.2000 [14]). This way for our country as a member of the World Organization does not contradict the requirements of this organization, since the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS) [15] suggests that member countries do not allow the patenting of diagnostic, therapeutic and surgical methods for treating humans or animals (paras. "A" ч. 3 article 27 of the Agreement).

The third option is a kind of compromise solution of the conflict of interests of the doctor and the patient and the owners of patents on the methods of treatment. It is about using the experience of the United States in this field. In this country, the methods of treatment and methods of diagnosing the human body since the middle of the XIX century. They were considered banned for patenting in accordance with the so-called Morton's judicial doctrine. Nevertheless, in 1952 the Patent Law was revised, which led the courts to change the case law, and medical methods became patentable without any restrictions on a par with other inventions [8, p. 128]. However, a new impact to the introduction of changes in the system of patenting of the treatment methods was the suit of the surgeon Pallini, who was the owner of the patent for the method of conducting a cataract operation without seams, to another surgeon due to the fact of patent infringement. This case received a significant response among health professionals.

For this reason, the American Medical Association expressed the view that doctors should not have difficulties associated with patent issues when they carry out their professional activities. However, the US Patent Office (USPTO) was not ready to enter into ethical discussions. In fact, it opposed any legislative ban on patenting. There were hearings on this issue at which the proposal to adapt US legislation to the European one was discussed. In order to resolve this issue, two legislative proposals were introduced. One, which is very close to European legislation, was the introduction of a ban on the patenting of medical methods; the other was to limit liability for infringing patents on medical methods. As a result, a new legislative amendment was adapted to paragraph 287 United States code, which exempts health professionals and organizations related to healthcare from the responsibility for using patented medical procedures, with the exception of drugs and devices [7, p. 12].

However, it should be noted that judicial practice introduces certain adjustments to the conditions for the admissibility of patenting the methods of treatment that are the basis for changing the balance of interests of the

"patient" – "owner of the patent." In particular, a modern understanding of the conditions for obtaining a patent for treatment methods is impossible without an analysis of their content for compliance with the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* In *Mayo* the Court essentially ruled out any natural relationship or correlation that "exists in principle apart from any human action"». [16]

Such a variant of the development of legal regulation in the medical sphere can be introduced in Ukraine, especially, taking into account the fact that with the receipt of patents for treatment methods in our state, there are also other legal consequences, except for the granting of patent protection. In particular, on the number of patents in the medical field received by a particular scientific institution, proceeding from the provisions of Art. 20 fundamentals of the healthcare legislation of Ukraine may depend on the size of the budget funding of this institution.

## CONCLUSION

Summing up, it seems necessary to determine at the scientific level the expediency of preserving the existing practice of patenting the methods of therapeutic and surgical treatment and methods of diagnostics applied to a person and choosing the most socially and economically feasible option for developing a mechanism of the legal regulation of patenting in this field with subsequent reproduction results in national legislation. The starting point, in our opinion, should be the need to create conditions for patients to access the latest developments and techniques in the medical field without increasing the cost of such treatment through licensing fees.

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