RGSA – Revista de Gestão Social e Ambiental
ISSN: 1981-982X
Data de submissão: 04/12/2023
Data de aceite: 04/03/2024
DOI: https://doi.org/10.24857/rgsa.v18n5-015
Organização: Comitê Científico Interinstitucional
Editor Chefe: Christian Luiz da Silva
Avaliação: Double Blind Review pelo SEER/OJS

MEDIATION IN PATENT DISPUTES ARISING IN THE HEALTHCARE SECTOR

Teremetskyi Vladyslav [1]
Tokarieva Kseniia [2]
Romas Mariia [3]
Bondarenko-Zelinska Nadiia[4]
Panchenko Sergii[5]
Maikut Khrystyna[6]
Batryn Olesia[7]

ABSTRACT

Purpose: The study is devoted to the analysis of mediation in patent disputes arising in the field of healthcare.

Methods: The research used general and special methods: dialectical method, methods of analysis and synthesis, formal-logical, system-structural method, and comparative-legal method.

Results and discussion: The results showed that innovative advances in medicine provide a new range of opportunities, but at the same time generate new legal challenges that require effective regulatory mechanisms. The main advantages of using mediation in patent disputes by medical companies remain the minimization of reputational risks and the confidentiality of information that becomes known to the mediator during the settlement of the conflict or dispute.

Implications of the research: The principles of confidentiality of medical information (including scientific and technical, commercial secrets, etc.), the principle of mandatory involvement of experts from the relevant field, the principle of medical ethics and high professional standards, the principle of matching the experience of the mediator to the level of complexity and the subject of the dispute will ensure the most effective resolution of patent disputes in the field of health care through mediation while maintaining the important elements of confidentiality of medical data, medical expertise, and professional ethical norms.

Originality/value: The use of mediation in such disputes is relevant within the framework of high competition, the pace of scientific achievements and the steady growth of the volume of medical innovations, therefore it requires new approaches and policies of introduction into legal systems.

Keywords: Mediation, Intellectual Property, Intellectual Property Law, Patent, Patent Disputes, Medicine, Health Care, Mediability, Mediator.

MEDIAÇÃO EM DISPUTAS DE PATENTES SURGIDAS NO SETOR DE SAÚDE

[1] National Academy of Legal Sciences of Ukraine, Kyiv, Ukraine. E-mail: vladvokat333@ukr.net
Orcid: https://orcid.org/0000-0002-2667-5167
[2] National Aviation University, Kyiv, Ukraine. E-mail: ph.d.tokarieva@gmail.com
Orcid: https://orcid.org/0000-0001-5705-5211
[3] Leonid Yuzkov Khmelnytskyi University of Management and Law, Khmelnytskyi, Ukraine.
E-mail: mariaromas11@gmail.com Orcid: https://orcid.org/0000-0003-3650-5409
[4] Leonid Yuzkov Khmelnytskyi University of Management and Law, Khmelnytskyi, Ukraine.
E-mail: flaming_n@ukr.net Orcid: https://orcid.org/0000-0002-8570-6920
[5] Law Office "Panchenko & Partners", Kyiv, Ukraine. E-mail: sergey.panchenko@ukr.net
Orcid: https://orcid.org/0000-0001-8257-0661
[6] Lviv State University of Internal Affairs, Lviv, Ukraine. E-mail: chrystyna.maykut@gmail.com
Orcid: https://orcid.org/0000-0002-2196-4023
[7] Pecherskyi District Court of Kyiv, Kyiv, Ukraine. E-mail: mysha-s@ukr.net
Orcid: https://orcid.org/0000-0001-9798-201X

RESUMO

Propósito: O estudo é dedicado à análise da mediação em disputas de patentes que surgem no campo da saúde.

Métodos: No estudo, foram utilizados métodos gerais e especiais: método dialético, métodos de análise e síntese, formal-lógico, método sistêmico-estrutural, método comparativo-jurídico.

Resultados e discussão: Os resultados mostraram que as inovações médicas fornecem um novo alcance de possibilidades, mas ao mesmo tempo geram novos desafios legais que exigem mecanismos eficazes de regulamentação. As principais vantagens do uso da mediação em disputas de patentes por empresas médicas permanecem a minimização de riscos reputacionais e a confidencialidade das informações conhecidas pelo mediador durante a resolução de conflitos ou disputas.

Implicações da pesquisa: Os princípios de confidencialidade da informação médica (incluindo segredos científico-técnicos, comerciais, etc.), o princípio da obrigatoriedade da participação de especialistas do campo relevante, o princípio da ética médica e dos altos padrões profissionais, o princípio da correspondência da experiência do mediador ao nível de complexidade e ao assunto da disputa permitirão garantir a resolução mais eficaz de disputas de patentes no campo da saúde através da mediação, mantendo ao mesmo tempo elementos importantes de confidencialidade dos dados médicos, expertise médica e normas éticas profissionais.

Originalidade/valor: A aplicação da mediação nessas disputas é relevante no contexto de alta concorrência, ritmo de conquistas científicas e crescimento sustentável dos volumes de inovações médicas, portanto, exige novas abordagens e políticas de implementação nos sistemas legais.

Palavras-chave: Mediation, Intellectual Property, Intellectual Property Law, Patent, Patent Disputes, Medicine, Health Care, Mediability, Mediator.

MEDIACIÓN EN LOS LITIGIOS SOBRE PATENTES QUE SURGEN EN EL SECTOR DE LA SALUD

RESUMEN

Finalidad: El estudio se dedica al análisis de la mediación en los litigios de patentes que surgen en el ámbito de la salud.

Métodos: En el estudio se utilizaron métodos generales y especiales: método dialéctico, métodos de análisis y síntesis, método formal-lógico, sistémico-estructural, método comparativo-legal.

Resultados y discusión: Los resultados mostraron que las innovaciones médicas ofrecen un nuevo abanico de posibilidades, pero al mismo tiempo generan nuevos desafíos legales que requieren mecanismos regulatorios efectivos. Las principales ventajas del uso de la mediación en disputas de patentes por parte de las empresas médicas siguen siendo la minimización de los riesgos de reputación y la confidencialidad de la información conocida por el mediador durante la resolución de conflictos o disputas.

Implicaciones de la investigación: Los principios de confidencialidad de la información médica (incluidos los secretos científico-técnicos, comerciales, etc.), el principio de participación obligatoria de expertos del campo pertinente, el principio de ética médica y altos estándares profesionales, el principio de correspondencia de la experiencia del mediador con el nivel de complejidad y el objeto de la disputa garantizarán la resolución más eficaz de las disputas de patentes en el campo de la salud a través de la mediación, manteniendo al mismo tiempo importantes elementos de confidencialidad de los datos médicos, experiencia médica y normas éticas profesionales.

Originalidad/valor: La aplicación de la mediación en estos conflictos es relevante en el contexto de alta competencia, ritmo de logros científicos y crecimiento sostenible de volúmenes de innovaciones médicas, por lo tanto, requiere nuevos enfoques y políticas de implementación en los sistemas jurídicos.

Palabras clave: Mediación, Derecho de Propiedad Intelectual, Patentes, Disputas de Patentes, Medicina, Atención Médica, Mediabilidad, Mediador.

1 INTRODUCTION

With the development of modern technologies and scientific discoveries, especially in the field of health care, the relevance of intellectual property and patent protection issues is increasing. Due to social changes and processes, patent disputes are becoming an integral part of the sphere of business and science. Within the limits of these disputes, mediation as a means of alternative conflict resolution becomes an important tool aimed at achieving a peaceful and effective resolution of disputes between the parties. This approach reflects modern trends in the resolution of legal disputes, contributing to the preservation of innovative potential and stimulating the further development of medical technologies.

The research aims to determine the effectiveness of mediation as a method of resolving patent disputes in the field of health care. Analyzing outcomes such as conflict resolution rates, best practices in the implementation of mediation in the health care context, it is possible to assess whether mediation is a valuable tool for conflict resolution in both medical and intellectual law disputes. A mediation institute can have a direct impact on the patient care process by resolving disputes related to treatment decisions, medical errors, and other healthcare issues. It is well known that in world practice, mediation affects the level of patient satisfaction and the overall quality of medical care.

Patent litigation, especially in healthcare, can be financially burdensome for all parties involved, including patients, healthcare providers, and insurance companies. The cost-effectiveness of mediation compared to traditional litigation will demonstrate its potential to reduce legal costs and preserve the resources of individuals and legal entities to carry out their traditional medical activities. Mediation also raises ethical considerations related to patient confidentiality, informed consent of the parties, and impartiality of mediators. Adapting existing models to the sensitive demands of healthcare disputes and fostering interdisciplinary collaboration between medical experts and conflict resolution professionals is important as it facilitates collaboration and innovation through pooled resources and capabilities, which is reflected in the further development of medical technologies and improving access to them.

2 THEORETICAL FRAMEWORK

World experience confirms the active use of mediation, including in patent disputes in the field of health care. For example, in the Netherlands, there is judicial mediation, which is quite effective in terms of statistics: about 95% of judges believe that mediation will help solve the problems of conflicting parties. At the same time, 60% of litigants agree to mediation after the first 2.5 hours are free. It should be noted that with a written referral, participation in mediation leads to a successful conclusion of agreements in 75% of cases (Bartusiak, 2020).

According to O. Klymenko, mediation is especially effective in situations where it is important to restore or preserve the relationship between the parties since maintaining interaction is an important factor for all interested parties (Klymenko, 2013).

A. Lysko supports the importance of using mediation in the field of health care. The author emphasizes that the use of mediation in this field has significant advantages due to the importance of social relations and the specificity of medical law. It also points to the importance of confidentiality as the main principle of mediation, which allows you to preserve information about health and medical secrecy (Lysko, 2018).

In the study of K. Tokarieva, it is noted that conflicts in the field of health care are characterized by increased psychological tension and a strong emotional burden for patients. The use of mediation in this field has such advantages compared to other methods of conflict resolution, such as voluntary participation of participants, equality and independence of the parties in decision-making, neutrality of the mediator, and preservation of confidentiality, which helps to preserve medical secrecy and the reputation of the medical institution (Tokarieva, 2020, p. 44).

3 METHODOLOGY

In the process of preparing the article, general and special methods were used. General methods include the dialectical method, methods of analysis and synthesis, which made it possible to investigate the legal nature of mediation and the peculiarities of patent disputes.

Special research methods made it possible to conduct an analysis of foreign experience and to investigate specific examples of patent disputes in the field of medicine. The formal logical method made it possible to investigate general provisions regarding the institution of mediation and patent law. The system-structural method made it possible to outline the types of disputes in the field of health care. A comparative legal method was used, which included a

review of regulations and literature related to mediation and patent disputes in the field of health care in different countries of the world. In particular, legislative acts of the European Union, the United States, Singapore, and Germany were subject to analysis.

4 RESULTS AND DISCUSSION

Before considering the specifics of mediation in patent disputes related to the healthcare industry, it is advisable to analyze the concept of mediation in the general sense.

A number of common interpretations have been revealed in the views of scientists regarding the definition of the concept of mediation. S. Zapara defines mediation as an alternative, voluntary way of resolving a dispute, which is based on contractual principles and, with the participation of a mediator, helps to reach a mutually acceptable solution (Zapara, 2015, p. 85). M. Polishchuk considers mediation as an alternative method of dispute resolution, the conditions of which provide for the voluntary participation of the parties in negotiations under the guidance of an independent and qualified mediator in order to reach a consensus and resolve the dispute (Polishchuk, 2014, p.138). V. Reznikova interprets mediation as the activity of neutral mediators, which is based on the principles of confidentiality, good faith, and equality of the parties with the aim of directing them to settle the dispute (Rieznikova, 2012, p.14). O. Kirdan summarizes the views of other scientists, pointing out the essence of the mediation mechanism as facilitating negotiations with the participation of a neutral mediator in order to reach mutually acceptable solutions and resolve disputes (Kirdan, 2019, p.17).

In the Law of Ukraine "On Mediation" dated January 16, 2021, mediation is defined as an out-of-court voluntary, confidential, and structured procedure, during which the parties, with the help of a mediator(s), try to prevent the occurrence or settle a conflict (dispute) through negotiations (On mediation, 2021, part 4 article 1).

Scientific studies conducted by O. Kirdan and M. Polishchuk contain common features and characteristics of the mediation mechanism. According to the conclusions of O. Kirdan, the mediator should play the role of a mediator in the process of information exchange, promoting understanding and joint search for a solution to the dispute between the parties (Polishchuk, 2014, p.138). In turn, M. Polishchuk points to the main features of mediation, which include regular negotiations between the parties or separate conversations with each of them, voluntary participation and conclusion of an agreement, management of the process by the mediator, and independent decision-making by the parties (Kirdan, 2019, p.17).

In view of the above, it should be summarized that the purpose of mediation is to facilitate the development of a mutually acceptable solution to the conflict between the parties through effective negotiations while ensuring the confidentiality and structure of the process. This method of dispute resolution is aimed at achieving mutual assistance and agreement between the parties, allowing them to independently make decisions that meet their interests and needs. This approach helps to build constructive relations and resolve conflicts without the need to be involved in court procedures.

Achieving a balance between the legislative framework of Ukraine in the field of mediation and international standards, in particular, the recommendations of the Council of Europe plays an important role in the development of mediation in various fields. If the normative legal regulation of mediation in Ukraine is unified and does not directly distinguish the specifics of its application to various types of disputes, then the Committee of Ministers of the Council of Europe provides recommendations on the use of mediation in various fields. Among them are recommendations for the application of mediation in such areas of law as civil law, family law, labor relations, commercial disputes, and others. They contain provisions to encourage the use of mediation as an effective and expeditious means of conflict resolution and also define the principles and procedures to be followed in the mediation process.

Recommendation Rec (2002) 10 of the Committee of Ministers of the Council of Europe to member states on mediation in civil cases defines recommendations regarding the use of mediation in civil cases, which, in the sense of the document, relate to cases related to civil rights and obligations, with the exception of administrative and criminal ones (On Mediation in Civil Matters, 2002). Based on the nature of civil-law relations and the scope of application of the Recommendation, we can conclude that disputes of a private legal nature arising in the field of health care can be the object of relations formed in the process of applying mediation. This document provides a framework and recommendations for the organization and conduct of the mediation process aimed at effective conflict resolution. Similarly, the framework legal act that should be taken into account when determining the basis for the application of mediation in health care disputes is Directive 2008/52/EC of the European Parliament and of the Council of Europe "On certain aspects of mediation in civil and commercial matters", the purpose of which is facilitating access to alternative dispute resolution methods, encouraging the use of mediation and ensuring a balanced relationship between mediation and litigation in civil and commercial matters (About some aspects of mediation in civil and economic legal relations, 2008).

Due to the characteristic features of mediation and the principles of its implementation, it can adapt to the requirements of various disputes arising in the field of health care. According

to Article 4 of the Law of Ukraine "On Mediation", mediation is conducted in accordance with the principles based on the mutual consent of the parties and includes the principles of voluntariness, confidentiality, neutrality, independence, and impartiality of the mediator, as well as the principles of self-determination and equal rights of the parties (On mediation, 2021, article 4). According to the research of O. Mozhaikina, the principles of mediation in civil disputes include additional principles, in particular the principle of personal responsibility, awareness, structure and flexibility of the mediation process, as well as the openness of the result (Mozhaikina, 2017, p. 57).

The Institute of Mediation plays a significant role in resolving medical conflicts and establishing harmonious relations between doctors, patients, and other interested parties. Various disputes arise in the medical field, such as the poor-quality provision of medical services, violation of patients' rights, conflicts between medical staff and hospital administration, conflicts related to medical diagnosis, treatment, resource allocation, etc. One of the key advantages of mediation in this field is that it allows the parties to maintain confidentiality and control over the conflict resolution process. In addition, the mediator, as a neutral third party, can help reduce emotional tension and build cooperation between the parties to reach a mutually beneficial solution.

In the researched field of law, mediation helps to reduce the number of court cases, effectively resolve conflicts, and ensure a fair compromise between the parties. It also saves the resources and time of all interested parties, avoids long and tedious legal processes, and preserves the reputation of medical professionals and healthcare institutions.

Among the advantages of mediation, researchers note that it allows all interested parties, including the patient, their parents, and other representatives (in the case of minors), to participate in a more creative way than can be the case in court. The mediator, working with the parties, adapts all elements of the mediation process to the needs of all participants and ensures that each voice is heard. Effective participation in mediation can help patients and their families resolve the underlying issues that form the basis of the conflict and help health professionals fully understand the positions of the other participants (Lindsey; Doyle; Wazynska-Finck, 2023, p.).

At the same time, certain types of disputes in the field of health care, including disputes regarding intellectual property rights, require separate approaches to ensure their mediaability. Thus, scientists point out that mediators with low qualifications can cause parties (individuals and legal entities) who turn to mediation for the first time to quickly come to the conclusion that the whole process is inferior and not worth trying again (Antolak-Szymanski; Cărăbaş,

2023, p. 7). Considering the above, it is important to take into account the importance of specialization and qualification of mediators. Patent litigation in the field of medicine and healthcare often requires an understanding of technical, scientific, and legal aspects. Insufficient qualifications of the mediator may lead to an incomplete understanding of the complex legal elements of the patent case or individual medical details, which may undermine the confidence of the participants in the process. The competitive environment of mediators from among professional lawyers or officials of a specially created mediation body will make their services high-quality and accessible to the public. To date, the mechanisms for the certification of mediators in different countries remain quite different, so monitoring the education, experience, and skills of mediators is a difficult task (Teremetskyi; Tokarieva, 2023, p. 206).

To prevent such situations, it is necessary to ensure that mediators working in the field of health care have the appropriate skills and competence, including an understanding of patent law, medical issues, and the specifics of the given field. Conducting specialized training and certification for mediators who work in this direction can be a useful step to ensure the high quality of the mediation process and maintain the parties' confidence in its results. In addition, it is important to ensure that the parties have the opportunity to choose an experienced and appropriately qualified mediator in order to guarantee the success of the mediation process and the achievement of long-term solutions that take into account their interests and needs.

The mediation process has other risks that are relevant to medical disputes with a strong emotional component. In particular, one of the parties may be unwilling or even unable to actively participate in the process due to the presence of psychological or physical obstacles. It is also worth considering the possibility that one party may be interested only in revenge, which makes it difficult to reach a constructive solution (Klein, 1996, p.458) (for example, in the case of the death of a loved one due to a medical error).

Therefore, in the field of health care, there are various types of disputes, which, taking into account specific features, can be resolved through mediation. Disputes may arise between a doctor and a patient in the field of pharmaceuticals regarding the protection of personal data, moral damage caused to the patient, etc. Over time, the relevance of mediation in this field remains high, but there are changes in the frequency of its use in relation to certain subjects of conflict.

For example, in 2011, researchers indicated that mediation is commonly used to resolve disputes between companies in the healthcare industry. Healthcare providers, payers, managed care companies and other health-related companies have been the subjects of such disputes. Healthcare lawyers with experience in arbitration and mediation handle a variety of disputes,

including compensation claims, healthcare contract disputes, and managed care matters. Notably, business-to-consumer disputes, particularly those related to long-term care, have been relevant in this sector of the healthcare industry (Gantz; Gupta; Sao, 2011, p. 35).

Scientists note that disputes in the medical field are not limited to interactions between doctors and patients. In daily practice, conflicts and misunderstandings arise between medical personnel, namely doctors, regarding the order of interaction and spheres of responsibility. In addition, there are conflicts between medical personnel and the administration of medical institutions, as well as in relations with representatives of the pharmaceutical industry. Successful cases of the use of mediation in the medical field are recorded in the fields of dentistry, cosmetology, and plastic surgery. The use of a mediation approach in these segments allows for effective resolution of conflicts and provides positive results, contributing to maintaining reputation and increasing trust in the patient environment (How to use mediation in medical disputes, 2018).

It should be noted that mediatable disputes can be those that arise between large pharmaceutical companies fighting for the rights to patents and the development of medical drugs or technologies. Disputes between manufacturers of medical equipment and doctors related to the use of the latest technologies or the implementation of innovative treatment methods can also be included in mediatable disputes. In health care, disputes between doctors and patients, as well as internal conflicts in medical institutions, such as between medical staff and administration, can be considered mediatable. This especially applies to situations where there is a misunderstanding or a conflict of interests that can be effectively resolved through constructive dialogue and cooperation between the parties.

Regardless of the scale of this or that conflict or dispute, its subject, and the number of participants, when determining the mediability of relations, it is important to consider that all parties must be ready for constructive dialogue and strive to achieve mutually beneficial solutions.

Regarding patent disputes, the European Commission in its annual report for January 2020 noted Ukraine as one of the biggest violators of intellectual property rights, in particular, in the field of medicinal products (Patent wars: how Ukrainian pharmaceuticals protect their intellectual rights, 2018). The report of the Supreme Court on the decrease in the number of cases in the category of intellectual property in 2022 in conditions of war (Patent disputes during the war, 2023) shows that patent disputes are marked by high activity, despite the complexity of the times. The practice of the Supreme Court also shows that there is a significant number of disputes over patents in the field of health care, including medicinal products.

International law recognizes the right to the protection of moral and material interests as a result of any scientific, literary, or artistic activity, including products, the author of which is a person. In particular, point "c" part 1 of p. 15 of the International Covenant on Economic, Social and Cultural Rights gives every person the right to enjoy the protection of such interests (International Covenant on Economic, Social and Cultural Rights, 1996).

Ukraine, as a party to international agreements, recognizes these principles. According to the Law of Ukraine "On Protection of Rights to Inventions and Utility Models", any violation of the rights of the patent owner, provided for in Art. 28 of this Law, is considered a violation that entails responsibility in accordance with the current legislation of Ukraine (On protection of rights to inventions and utility models, 1993, part 1 article 34).

Thus, patent infringement occurs when a person who can be identified as an infringer uses an invention or utility model without obtaining the consent of the relevant subject of patent rights, which is the patent owner or its successor. Consent to use can be acknowledged by entering into an appropriate agreement, such as a license agreement or agreement on the transfer of exclusive rights. The license, in turn, serves as a written confirmation of the right to use the invention or utility model and defines the conditions under which this use can take place.

The described process is key in the patent system, where the protection of the patent owner's rights is provided by his exclusive right to control the use of the invention. In other words, the assignee or owner of the patent has the legal right to decide who and under what conditions may be allowed to use said invention or utility model. This process is regulated by relevant legal agreements, which determine the scope and conditions of use and ensure rational and fair use of the patented object.

In view of the above articles and legislation, patent disputes in the field of health care may arise in cases of infringement of patent rights related to medical inventions, drugs, equipment for medical use, and other technologies used in medical practice. Disputes of this nature may concern the right to an invention, its use, production, trade, and other aspects defined by patent legislation.

There are different types of patents, each of which has its own specific term of validity. The first type is a patent for an invention, the term of which is 20 years. The second type is a utility model patent valid for 10 years. The third type of patent is a patent for an industrial design, valid for 15 years. It is worth noting that an invention or utility model can be not only a specific product or process but also a new application of an existing product or process. While an industrial design does not refer to an invention or a utility model, but is a solution in the field of artistic design (Izhevska, 2018).

Yu. Kolchenko rightly points out that the judicial practice in Ukraine regarding patent disputes covers several main categories. The first category includes disputes related to infringement and cessation of infringement of patent rights, as well as compensation for damages. The second category covers patent invalidation disputes based on lack of novelty, inventive step or industrial applicability. The third category includes disputes related to the invalidation of registrations of medicinal products or plant protection products due to infringement of patent rights. The latter category covers disputes relating to the infringement of rights to registration information for medicinal products, such as data exclusivity (Kolchenko, 2018, p.14).

Patent disputes of the first category may arise in cases where a person, without the permission of the relevant patent owner, uses an invention protected by a patent. This category covers conflicts related to the use and implementation of medical inventions, medicines, equipment, and other technologies used in the field of medicine.

A significant element in such disputes is the resolution of issues related to the facts of infringement of patent rights and the establishment of conditions for their termination. Patent owners often go to court to protect their intellectual property, especially when it becomes known that their designs or technologies are being used illegally in the healthcare sector. Judicial practice in this area demonstrates a thorough investigation of the facts of infringement of patent rights. The scope of such violations is ascertained and the damages caused to patent owners are determined. In cases where infringement of patent rights is recognized, the court determines the necessary measures to stop the infringements and establishes compensation for damages.

Disputes related to the recognition of patents as invalid are an important element of patent law and are often based on the lack of novelty, inventive step, or industrial applicability of an invention or utility model. According to Part 4 of Art. 33 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models", which defines the rules of invalidity of a patent, if the rights to an invention (utility model) are recognized as invalid in a court of law, these rights are considered to have not entered into force (On protection of rights to inventions and utility models, 1993).

The date of publication of information on the state registration of an invention or utility model is used to establish the moment when intellectual property rights become invalid. This date is similar to the date of state registration, as both actions must be carried out simultaneously. Thus, from the point of view of the right-affirming value, it is not the patent itself that becomes more important, but the record of the state registration of the corresponding rights, which are

recognized as invalid. It is completely logical that the recognition of the rights to an invention (utility model) as invalid has as a consequence the invalidity (invalidity) of the patent that testifies to these rights, or its parts relating to specific independent or dependent clauses of the formula, the rights to which are recognized to be invalid.

E. Hareev considers the grounds for declaring a patent invalid, including non-compliance of the patented invention with the conditions of patentability, the presence in the claims of the invention of features that were not submitted in the application, violation of requirements for foreign patenting and patent issuance due to violation of the rights of other persons. It points out the consequences for patent holders, such as significant production costs, because after the patent is invalidated, other companies can produce similar products without compensation. Also considered are situations where an employer applies for a patent after paying a fee to the inventor, or when a patent is issued to a person who did not have the right to do so, which can lead to significant losses for those who use the invention. Special attention is paid to declaring a patent invalid in case of violation of the legislation of another country when registering a patent abroad (Hareev, 2008, p.38-40).

In healthcare patent litigation, situations in which a patent for a medical invention is declared invalid may arise, for example, when a dispute arises regarding the novelty or inventive step of a medical drug or technology. A significant number of medical patent disputes may also arise from competition between pharmaceutical companies developing similar drugs or treatment technologies. Such disputes often include objections to the novelty and inventive step of an invention, as well as issues of patent infringement. The regulation of such relations is of great importance for the development of medical science and the possibilities of treating various diseases.

An example of an international patent dispute is the conflict between the University of California at Berkeley and the Broad Institute, generated by gene editing technology CRISPR-Cas9. The dispute serves as an illustration of how differences in patent prosecution rules can determine the priority and scope of patent rights related to an invention that revolutionizes gene editing. Disputes that have been ongoing for almost a decade have revealed important aspects of the determination of priority rights and the scope of patent rights in different jurisdictions. CVC and the Broad Institute initially filed conflicting patent applications claiming rights to use CRISPR-Cas9 technology in eukaryotic cells, and the dispute escalated. Over the years, the CVC group has tried to establish its priority in the development of the technology, but the USPTO's decision in favor of the Broad Institute in interference cases indicates that the Broad Institute is considered the original inventor. However, the dispute received different solutions

in Europe and the United States. The CVC group succeeded in exploiting the difference in patent rules and invoking the Broad Institute's priority. The absence of the name of the inventor Luciano Marrafini in the Broad Institute's European patent application played a big role in this. Under strict European rules, priority claims were insufficient, leading to CVC's victory and the invalidation of the Broad Institute's patents in Europe (Davitz *et al.*, 2024).

The third category of patent disputes, in general, is similar to the previous one and refers to situations when medicinal products or plant protection products that have been registered by the patent owner are called into question due to possible infringements of patent rights. In such disputes, the main issue is the recognition of patent invalidity due to proving the fact of wrongful assignment of patent rights or violation by the patent owner of established conditions relating to novelty, inventive steps, or other patent law requirements. Disputes in this category often arise in the pharmaceutical and agricultural industries, where competition is high and patent rights for new drugs or plant protection products are key to market success and intellectual property protection.

The fourth category of patent disputes includes disputes arising from infringement of rights to registration information for medicinal products, such as data exclusivity. Such disputes usually arise in connection with competition between pharmaceutical companies for the right to exclusive use and marketing of new medicinal products. Issues may relate to the refusal to issue or withdrawal of exclusive status for a certain medicinal product, as well as non-compliance with the requirements for the preservation of confidentiality and use of registration data in accordance with the rules and conditions of license agreements. Disputes of this category have a significant impact on access to new medicines on the market, as well as on the competitiveness of companies in the pharmaceutical industry.

In today's legal environment, it is worth noting that it is necessary to approach the analysis of patent disputes more broadly than simply applying the described categories. It should be borne in mind that the number and types of patent disputes are constantly changing and expanding, reflecting the dynamic nature of innovative development and technological progress. New inventions, changes in legislation, judicial practice, and international norms can create new contexts and reasons for the emergence of patent disputes, which may differ in their specificity from already known categories. Therefore, when analyzing and managing patent disputes, it is important to have a flexible approach and readiness to adapt to new challenges and situations arising in the field of intellectual property.

Due to the seriousness of patent disputes, it is important to note that mediation can be an effective tool for resolving intellectual property disputes. Although mediation is not possible

for all patent disputes, as some of them can be extremely complex and require a high level of expertise, in simpler situations this method can help to reach a quick and mutually beneficial solution. Also, mediation cannot be used in cases where there is a violation of the legal norms regarding patenting.

Researchers believe that mediation can successfully resolve disputes related to the violation of intellectual property rights, as well as conflicts related to the licensing and transfer of rights to intellectual property objects, including ownership rights to inventions and other objects (Vasyurenko *et al.*, 2022, p.10).

We believe that the introduction of mediation in the field of intellectual property can significantly reduce the costs of time and resources traditionally associated with litigation. The involvement of a neutral mediator contributes to the creation of a constructive dialogue between the parties aimed at finding mutually beneficial solutions and avoiding the costs of long-term and exhausting legal procedures. Given the rapid pace of development of a variety of intellectual products, the effectiveness of mediation becomes an urgent need.

The positive aspect lies not only in the importance of saving time but also in the pragmatism of the mediation process, as the decision made in mediation often takes into account the specifics of the specific situation and the needs of both parties. In addition, a court decision is not always followed by its effective implementation, while mediation can facilitate an agreement that takes into account the interests of both parties and increases the likelihood of the implementation of agreed agreements. Litigation often has a negative impact on the reputation of the parties, while the mediation process creates an opportunity to come together and resolve the conflict in a mutually beneficial way, which can be especially important in the field of intellectual property, where reputation and creative exchange can be critical elements of success.

It is worth noting that Ukraine is characterized by an insufficient level of mediation in the field of intellectual property. M. Lohvinenko, who analyzed mediation processes in other countries in the field of intellectual property rights protection, concluded that this method of conflict resolution is effective and beneficial for both parties (Lohvinenko, 2019, p.106).

In the United States of America, there is legislation that facilitates the resolution of disputes through mediation in the field of intellectual property. Under the Alternative Dispute Resolution Act 1998, courts have an obligation to use alternative methods of resolving civil cases, including mediation. This provision opens up opportunities for confidential dispute resolution without the need to review the case in court. In addition, there are private mediators

in the United States who specialize in intellectual property (Alternative Dispute Resolution Act, 1998).

Singapore is noted for its advanced mediation system, which is very effective in resolving disputes in the area under study. Under Singapore's Mediation Act 2017, the WIPO Center acts as the leading provider of mediation services in the country. The said institution has an excellent reputation in the settlement of conflicts, in particular in the field of intellectual property and technologies, which are often considered by judicial institutions. Parties to disputes are given the opportunity to choose a mediator from among the qualified specialists of the WIPO Center, which promotes an objective and professional approach to conflict resolution. After successful mediation by a mediator, the agreement reached by the parties can be recognized by a Singapore court as a decree, giving it legal force and the possibility of direct enforcement (Mediation for Intellectual Property and Technology Disputes Pending before Courts in Singapore).

As members of the WIPO, German entities involved in intellectual property disputes have the opportunity to challenge alternative dispute resolution methods established by the WIPO. These methods include mediation, arbitration, and expert determination procedures, which are considered out of court and can cover both domestic and international intellectual property disputes. Mediation can be used if the parties express a desire to resolve the conflict by agreement. Arbitration ensures that the arbitrator's decision is enforced. In the event of an unsettled conflict, the parties may apply to a German court, particularly a criminal court for consideration of infringements of intellectual property, which are considered criminal acts, especially in the context of piracy (Resolve Intellectual Property Disputes in Germany, 2016).

In conclusion, it can be stated that mediation is an extremely effective and promising tool for solving patent medical disputes. Foreign experience, particularly in countries such as Singapore, the United States of America, and Germany, shows the success of mediation in such an important area of intellectual property.

In patent disputes, where the disputes are often related to technical elements and scientific and medical issues, mediation allows the parties to interact constructively and resolve conflicts, avoiding costly and lengthy litigation. Private mediators who specialize in the field of patents and medicine can effectively facilitate the development of mutually beneficial solutions and agreements that satisfy the interests of both parties.

One of the key advantages of mediation in medical patent disputes is the confidentiality of the process, which allows the parties to freely discuss their positions and reach compromises without the public leak of confidential information. In our view, this is particularly important

in the field of intellectual property, where confidentiality and trade secrets are of strategic importance.

The use of mediation in patent medical disputes helps speed up the resolution of disputes, resolve intellectual property issues, and create an environment more conducive to innovation. Mediation provides flexibility and an individual approach to each case, taking into account the peculiarities and needs of the parties. This approach contributes not only to the reduction of time and resources but also creates incentives for further innovative activity in the field of patent protection of medical inventions.

According to V. Kroitor, the use of mediation procedures in the field of intellectual property law requires changes to the relevant legislation. These changes should concern both the mediation procedure and the legal environment. The main goal is to create clear norms, define the rights and obligations of the parties, and determine the competence of mediators. Active measures are also recommended to support the parties in engaging in mediation, as well as conducting detailed scientific studies on the effectiveness of mediation in intellectual property cases, particularly within the framework of copyright and industrial property (Kroitor, 2023, p. 127).

5 CONCLUSION

In the field of health care, there is a significant number of various patent disputes arising in connection with the rapid scientific and technical progress in the modern world. The urgency of this problem is determined not only by the high degree of competition but also by constant changes in the innovative landscape of the field of medicine. The wide variety of categories of patent disputes, ranging from infringements of intellectual property rights and licensing to conflicts related to the protection of drug registration information, creates complex challenges for the resolution of conflicts and disputes in this field.

Innovative advances in medicine provide a new range of opportunities, but at the same time, they generate new legal challenges that require effective regulatory mechanisms. Changing over time, the structure and nature of patent disputes in health care are determined by the dynamics of the development of modern scientific research and medical technologies. Thus, the issue of settling various categories of patent disputes in this sector requires not only a structured but also a functional approach, as well as adaptation to the current challenges and needs of the modern innovation environment.

The main advantages of using mediation in patent disputes by medical companies remain the minimization of reputational risks and the confidentiality of information that becomes known to the mediator during the settlement of the conflict or dispute. It is difficult to overestimate the importance of business reputation among pharmaceutical companies and manufacturers of medical equipment and technology, as it is about the trust of patients and consumers, the attraction of talented personnel for quality scientific research and inventions, investment attractiveness, and sustainability of the business. In turn, ensuring the confidentiality of information that constitutes a commercial secret will contribute to the establishment of competitive advantages for each subject of the medical services market, prevention of interference by third parties in the process of developing unique and effective medical solutions, protection of technologies and innovations, etc.

On the basis of the general principles of mediation, which must be considered when applied in patent disputes in the field of health care, it is possible to form special principles of procedure during the resolution of patent disputes. Among them are the principles of confidentiality of medical information (including scientific and technical, commercial secrets, etc.), the principle of mandatory involvement of experts from the relevant field, the principle of medical ethics and high professional standards, the principle of matching the experience of the mediator to the level of complexity and the subject of the dispute. Taking into account such principles will ensure the most effective resolution of patent disputes in the field of healthcare through mediation while preserving important elements of confidentiality of medical data, medical expertise, and professional ethical norms.

Mediation in patent disputes arising in the field of health care covers a significant and promising mechanism for the resolution of conflicts in the field of intellectual property. The use of mediation in such disputes is relevant within the framework of high competition, the pace of scientific achievements, and the steady growth of medical innovations.

REFERENCES

ALTERNATIVE Dispute Resolution Act of 1998. 1998. Available from: https://www.congress.gov/bill/105th-congress/house-bill/3528/text. Accessed: 26 Feb. 2024.

ANTOLAK-SZYMANSKI, Katarzyna; CĂRĂBAȘ, Mihai. The Qualifications of Mediators in Civil Matters, Including Employment Disputes, in Poland and Romania. *Review of European and Comparative Law*, no. 2, p. 7-26, 2023.

BARTUSIAK, Pavlo. *Judicial mediation: the experience of the Netherlands.* 2020. Available from: https://law.chnu.edu.ua/prysudova-mediatsiia-dosvid-niderlandiv/. Accessed: 25 Feb. 2024.

DAVITZ, Michael et al. *Specialist Chapter: Trends and Strategies in Global Pharma and Biotech Patent Litigation.* 29 Jan. 2024. Available from: https://www.iam-media.com/review/the-patent-litigation-review/2024/article/specialist-chapter-trends-and-strategies-in-global-pharma-and-biotech-patent-litigation. Accessed: 26 Feb. 2024.

EUROPEAN UNION. Committee of Ministers of the Council of Europe. Rec (2002)10, of 18 September 2002. *On Mediation in Civil Matters.* Available from: https://hcj.gov.ua/sites/default/files/field/rec_2002_10_2002_09_18_1.pdf Accessed: 25 Feb. 2024.

EUROPEAN UNION. The European Parliament and of the Council. Directive no. 2008/52/ЄС, of 21 May 2008. *About some aspects of mediation in civil and economic legal relations.* Available from: https://ukrmediation.com.ua/images/DOCS/Model-documents/mediation-directive-ukr.pdf. Accessed: 25 Feb. 2024.

GANTZ, David A.; GUPTA, Amar; SAO, Deth. Disputes related to healthcare across national boundaries: the potential for arbitration. *Arizona Legal Studies*, no. 11-24, c. 1-71, 2011.

HAREEV, Yevhenii. Grounds for recognition of intellectual property rights to inventions as invalid. *Actual problems of state and law.* no. 38, p. 37-41, 2008.

HOW TO use mediation in medical disputes. 4 Apr. 2018. Available from: https://medplatforma.com.ua/article/1415-medatsya-v-medichnih-sporah-yak-zastosovuvati. Accessed: 25 Feb. 2024.

INTERNATIONAL Covenant on Economic, Social and Cultural Rights of 16 December 1966. Available from: https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights. Accessed: 26 Feb. 2024.

IZHEVSKA, Marina. *What types of patents are there and what is the difference?* 8 Jan. 2018. Available from: https://wisegroup.com.ua/ua/vidi-patentiv/. Accessed: 26 Feb. 2024.

KIRDAN, Olena. The concept of «mediation» and approaches to its interpretation in modern scientific discourse. *Volyn Pedagogical Journal*, no. 2, p. 12-20, 2019.

KLEIN, Cathy A. Alternative dispute resolution in health care. *AORN Journal*, no. 63(2), p. 457-459, 1996.

KLYMENKO, Olena. Mechanisms of the conflict in health care. *Public administration: improvement and development*, no. 8, 2013. Available from: http://www.dy.nayka.com.ua/?op=1&z=680. Accessed: 25 Feb. 2024.

KOLCHENKO, Yulia. *Patent disputes in the field of pharmaceuticals*. These – Association of Lawyers of Ukraine, Kyiv, 1 Nov. 2018. Available from: https://uba.ua/documents/events/2018/20181101/Kolchenko.pdf. Accessed: 26 Feb. 2024.

KROITOR, Volodymyr. Mediation as alternative mean for resolving disputes in the field of protecting rights to atypical objects of copyright law. *Legal scientific electronic journal*, no. 8, p. 124-127, 2023.

LINDSEY, Jaime; DOYLE, Margaret; WAZYNSKA-FINCK, Katarzyna. Navigating conflict: The role of mediation in healthcare disputes. *Clinical Ethics*, 2023. Available from: https://doi.org/10.1177/14777509231196699. Accessed: 25 Feb. 2024.

LOHNINENKO, Mykola. Features of the step-by-step implementation of mediation in the sphere of intellectual property: prospects for Ukraine. *Law and innovation*, no. 6, p. 100-108, 2019.

LYSKO, Anna. *Mediation in the field of health care.* 25 Apr. 2018. Available from: https://mediation.lviv.ua/2018/04/25/медіація-у-сфері-охорони-здоровя/. Accessed: 25 Feb. 2024.

MEDIATION for Intellectual Property and Technology Disputes Pending before Courts in Singapore. Available from: https://www.wipo.int/amc/en/center/specific-sectors/ipoffices/national-courts/singapore/index.html. Accessed: 26 Feb. 2024.

MOZHAIKINA, Olena. The concept and content of the main principles of mediation in civil legal relations. *Actual problems of domestic jurisprudence*, no. 5, p. 55-58, 2017.

PATENT disputes during the war. Practice of the Supreme Court. 26 Jan. 2023. Available from: https://ips.ligazakon.net/document/EA016348. Accessed: 26 Feb. 2024.

PATENT wars: how Ukrainian pharmaceuticals protect their intellectual rights. 15 Feb. 2018. Available from: https://mind.ua/publications/20207868-patentni-vijni-yak-ukrayinska-farmacevtika-zahishchae-svoyi-intelektualni-prava. Accessed: 26 Feb. 2024.

POLISHCHUK, Mariia. The concept of mediation as an alternative method of dispute resolution. *State and law. Legal and political sciences*, no. 65, p. 134-139, 2014.

RESOLVE Intellectual Property Disputes in Germany. 26 May 2016. Available from: https://www.lawyersgermany.com/resolve-intellectual-property-disputes-in-germany. Accessed: 26 Feb. 2024.

RIEZNIKOVA, Victoriia. Mediation as a way of resolving business disputes. *Bulletin of Taras Shevchenko Kyiv National University. Legal sciences*, no. 90, p. 10-15, 2012.

TEREMETSKYI, Vladyslav; TOKARIEVA, Kseniia *et al.* Mediation in administrative and legal disputes in Ukraine: a European perspective. *Revista Amazonia Investiga*, no. 70, p. 200-209, 2023.

TOKARIEVA, Kseniia. Mediation in health care disputes. *Our right*, no. 4, p. 39-46, 2020.

UKRAINE. The Verkhovna Rada of Ukraine. Law of Ukraine no. 1875-IX, of 16 November 2021. On mediation. Available from: https://zakon.rada.gov.ua/laws/show/1875-20#Text. Accessed: 25 Feb. 2024.

UKRAINE. The Verkhovna Rada of Ukraine. Law of Ukraine no. 3687-XII, of 15 December 1993. *On protection of rights to inventions and utility models*. Available from: https://zakon.rada.gov.ua/laws/show/3687-12#Text. Accessed: 26 Feb. 2024.

VASYURENKO, Oleg *et al.* Mediation as an alternative way of resolving disputes in the field of intellectual property. *Bulletin of economic sciences of Ukraine*, no. 1, p. 9-14, 2022.

ZAPARA, Svitlana. The concept of mediation and features of its formation in Ukraine and the world. *Comparative and analytical law*, no. 3, p. 83-85, 2015.