THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS IN THE FIELD OF BIOMEDICINE IN UKRAINE

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ABSTRACT

The article is devoted to the research of the protection of intellectual property rights in the field of biomedicine in Ukraine. The relevance of the research is justified by the fact that one of the functions of the country is the protection of public health, which includes both the search for new drugs and methods of treatment and minimizing the negative impact from the existing ones, including those that are patented. It has been identified that the patenting is one of the most common ways to protect intellectual property rights in the biomedical field, though it is not entirely perfect. It is determined that Ukraine has one of the first places for the number of patents issued in class A61 (medical or veterinary science; hygiene) for the total number of patents. That fact indicates that the shortcomings of the patent legislation in the country impact on the situation that the patents are registrated for the objects that poorly meet the criteria of the patentability. It has been found that one such drawback is the ability of patent entities to establish a monopoly on the patented objects.

It is concluded that no perfect alternatives to patenting in the field of biomedicine have been proposed yet. It is noted, that the discussions on the issue of the creation of the state funding for biomedical researches and developments are underway, but the existence of such a mechanism in Ukraine is still in doubt. The particular attention is paid to the procedure of bringing the patenting mechanism in Ukraine into line with the requirements of Ukraine's accession to the Association Agreement with the EU, and the ratification of a number of international intellectual property acts. In this case, the innovations related to the strengthening of the patentability criteria, the updating the list of inventions for which a patent can be obtained, the introduction of the Bolar exemption, the possibility of appealing a patent's application, similar to the existing positive practices of India, where there is a tendency to grant patents, which make the country competitive in various fields, including biomedicine.

Keywords: Intellectual Property, Biomedicine, Medical Technologies, Patent Object, Patent, Evergreen Patents, Patentability.

INTRODUCTION

One of the functions of each state is to protect the health of its citizens, including the provision of medicines, the application of new methods of curing, including the number of

innovative technologies, but their development is carried out by persons who intend to obtain exclusive intellectual property rights for them, which is not always beneficial for the state and society. Only the owner of the intellectual property right has the right to dispose of the intellectual property, including giving permission for its use to others. Against this background, the current concept of protection of intellectual property rights in the field of biomedicine needs to be revised. Another issue that needs to be taken into consideration is the problem of protection of human rights and freedoms when testing developed drugs, methods and technologies. In particular, the Law of Ukraine "*On scientific and scientific and technical activities"* stipulates the obligation of a scientist, in carrying out scientific, scientific-technical and scientific-pedagogical activity, not to harm human health, his life and the environment, to respect ethical norms of the scientific community, to respect the right of intellectual property (Law of Ukraine, 2015).

Problem Statement

The realization of the health care function of state entails not only the task of developing new medicines, methods of treatment, etc., but also the task of ensuring the protection of the intellectual property rights of the inventors. Therefore, the state faces a complex task that must take into account the interests of society, inventors, the state, and therefore it is obvious that the issue of protection of intellectual property rights in the field of biomedicine in Ukraine is relevant and needs being studied.

LITERATURE REVIEW

Pyatchanyna et al. point out that the progress and the competitiveness in the field of biomedical researches are achieved today through the development of innovative biological, medical, pharmaceutical science-intensive technologies and scientific and technological developments resulting from the implementation of the research and projects. The rapid development of medical and biological sciences and the demand for research results in this field contributes to the commercialization and accelerating pace of implementation of a large number of innovative products in health care practices, which increases the efficiency of diagnostics and treatment (Pyatchanyna et al., 2019).

The point of view of Joris et al. who have stated that the majority of researchers' efforts are focused on advancing the technical and scientific aspects of the invention, should be accepted. The development and implementation of the invention can be time-consuming and expensive. The costs associated with the clinical use and testing of a drug or device typically cost millions (or even billions) of dollars. The pharmaceutical companies typically record their expenders, at the same time the universities and the affiliated hospitals, on the base of which the biomedical researches take place, use their primary source of income, as well as secondary (sectorial) or tertiary (governmental) grants to fund the research projects. However, such funding is generally insufficient to develop a clinical product (Joris et al., 2017).

At present, there is no single position among the scientists on the best way to protect intellectual property rights in the field of biomedicine. Considering that one of the sub-sectors of biomedicine is bioinformatics, we propose to pay attention to the opinion of Kshitij, who notes that considering the complex nature of bioinformatics, it is difficult to offer the best protection of intellectual property rights to it. Therefore, there is a debate about the suitability of forms of

intellectual property protection in the field of biomedicine, such as patent, copyright and trade secrets (Kshitij, 2014).

Ellen't Hoen points out that the government grants patents to persons who have invented something new, unknown and useful. In this case, a patent holder may prohibit others from making, using, importing or selling his invention for a certain period of time without his consent. Accordingly, the patent system is aimed to make a balance between the stimulating of innovations, the protecting of inventors' rights, and the providing of maximum benefit from innovations for the public (Ellen't, 2016).

METHODOLOGY

The research on the problem of the protection of the intellectual property rights in the field of biomedicine in Ukraine was carried out with the use of comparative-legal, system-structural methods and the method of critical analysis. Thus, the analysis of the latest scientific publications on the problem of the protection of the intellectual property rights in the field of biomedicine in Ukraine and in the world has executed due to the method of critical analysis and system-structural method. In addition, the method of critical analysis made it possible to identify the shortcomings of the current state of patenting in the field of biomedicine in Ukraine, and the comparative legal method was used to reveal in a comparative aspect the experience of patenting in the field of biomedicine in Ukraine and India.

FINDINGS AND DISCUSSIONS

As the patenting is one of the most common ways of the protection of the intellectual property rights in the field of biomedicine, it is worth paying attention to the percentage of the patents which were granted in Ukraine in class A61 (medical or veterinary science; hygiene) relative to the total number of patents: in 2013-12.7%, in 2014-13.1 %, in 2016-14.0%. The percentage of patents in the field of medicine from the total number of patents granted in WIPO's member states during the period from 2001 to 2016 is the following: the Republic of Belarus-6.36%, Ukraine-8.22%, the Republic of Moldova-13.33%, Israel-16.11%.

Kashyntseva also notes the statistic data in his researches. On the ground of the analysis of the World Intellectual Property Organization's Report for the period from 2000 to 2015, she notes that the share of national patents in the field of medical technologies in Ukraine is about 9.85%, and 5.5% for medicines. Whereas in Germany during the same period the share of patents granted in the field of medical technology in relation to other branches of technology is only 3.89%, for medicines-3,64%; in Poland, the share of national patents granted in the field of medical technology is 3.81%; in Austria-3.9%; in Spain-4.82%. At first glance, the percentage of patents granted in Ukraine is one of the highest among the European countries, which seems to be positive. At the same time, these data do not reflect the real situation on the health care of Ukraine, but only indicate the shortcomings of patent law, which leads to the issuance of weak patents in the field of medicine and pharmacy, which do not actually meet the existing standards of patentability (Kashyntseva, 2018).

Franjić notes that a patent can be granted for an invention in any field of technologies, if it is new, contains the inventive dimension and is capable of industrial application. The maximum term of protection is 20 years, which is far less than other ways of protecting intellectual property rights. However, the national legislation also provides the restrictions for

obtaining the patents on certain objects, including the inventions related to diagnostic or surgical procedures, treatments directly applicable to humans and animals, substances or compositions used in such procedures and methods (Franjić, 2017).

However, despite the imperfection of the system of the patenting of the intellectual property rights in the field of biomedicine, one cannot disagree with Pollack who considers that the patent gives the substantial protection of the rights of its owner. In particular, the monopoly position status of the pharmaceutical companies allows them to set sufficiently high prices for their medicines. For example, the price of tablets containing Daraprim purchased by Turing Pharmaceuticals increased from $13.50 up to $750 per pill in one night, which has led to an increase in the cost of treatment for some patients for up to a thousand dollars for one year. In addition, the price for drug Cycloserine went up from $500 per 30 tablets up to $10,800 per 30 tablets after it was purchased by Rodelis Therapeutics (Pollack, 2015). Similar is the statement of the Minister of Health, Welfare and Sport of the Netherlands, who emphasizes that the functioning of the pharmaceutical market causes the emergence of new medicines needed by the sick patients and obtaining patents on them. However, these patients are primarily disadvantaged by these patents because the pharmaceutical companies have a monopoly on new drugs. That's why, a healthy balance between the useful innovation and the availability of medicines must be found (Ministry of Public Health, 2016).

The most part of the opponents on obtaining patents on biomedicine as a guarantee of the protection of the intellectual property rights substantiate their position with its contradictory to the interests of the developing countries regarding their access to the medicines as well as to the provision of health care services by the state, especially for vulnerable, in particular children with special needs (Kulish et al., 2016). The considerable attention is paid to the protection of the interests of these entities, including the biomedical field in Finland, Norway, Denmark and France (Reznik et al., 2019). Speaking of Ukraine, only the first steps have been made in this direction.

Stephen point out that the enhanced protection of the intellectual property rights in the developing countries makes it possible to unlock the existing potential and it helps to overcome health challenges in the country and in the world. The cost of medicines is not the most serious problem in developing countries. To confirm this, one should pay attention to medicines from the World Health Organization's Model List of Essential Medicines, where 95% of active substances are available in the world without a patent. Accordingly, the problem of patenting in the field of the biomedicine is more likely interconnected with the undeveloped healthcare systems, the lack of actual access to rural health care. In other words, it is obvious that the patenting in the field of the biomedicine still has a number of advantages, at the same time the disadvantages are significant and require prompt response on them from the state.

However, as Helen Gubby points out, the perfect alternatives to the patenting system have not yet been proposed, but the possibility of introducing a comprehensive system of public funding for biomedical patenting is increasingly being discussed (Gubby, 2019). However, in the situation with the lack of funds in the state budget of Ukraine needed for financing the priority directions of the state development, there is no guarantee that it will be able to finance the development of the medicines and other objects in the field of biomedicine on its own.

That's why it is worth to pay attention to the conclusions of Suchita & Yogmaya, who advice to follow the experience of India, where there is a growing trend in patent applications. This is due to the existence of various schemes for financing the developments in India. In

particular, the biomedical developments that have the potential to make the Indian biomedical sector globally competitive can be financed simultaneously through private and public funding (Suchita & Yogmaya, 2017).

Kashyntseva determines that after Ukraine has signed the Association Agreement with the EU and ratified the international treaties in the field of intellectual property, including international patent law, in particular, the Paris Convention for the Protection of Industrial Property, the Patent Cooperation Treaty, The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Ukraine has undertaken a number of commitments. One of them is to bring the patenting mechanism in line with state-agreed requirements. At the same time, some of them have been implemented at least at the legislative level: the methods of diagnostics, treatment and surgery are excluded from the objects of patenting. However, the criteria for patentability of the pharmaceutical inventions should be strengthened with the prohibition of patenting of the new forms of the known modern drug or its any new property, the new uses of the known drug, with the exception for those that lead to a significant increase in the therapeutic efficiency of the medical product, that will be confirmed by the research results. This will help to avoid evergreen patents (Kashyntseva, 2018).

The need of counteraction to evergreen patents owes to the fact that not all new drugs are really new. Beall et al. note that some of them are the results of the gradual patenting of already existing products, but without significant therapeutic improvements. This phenomenon is known as evergreen patents which allow the manufacturers to preserve the market's exclusivity without significantly improving of treatment levels (Beall et al., 2016).

The implementation of the Bolar exemption should be also considered, this will allow the generic manufacturers to carry out studies and tests for regulatory approvals and other related actions for the preparation for a marketing authorization, getting additional certificates on the protection for the inventions as a legal tool for claiming patent rights, the ability to challenge the validity of a patent application on certain grounds, such as an innovative step, new results in treatment methods, new efficiency, etc. (Kashyntseva, 2018). Another way of counteracting to the evergreen patents is a compulsory licensing, which is present in low-income and middle-income countries, when the government licenses the intellectual property enforcement, including patents and copyrights. However, the use of the compulsory licensing is limited and sporadic, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) states that the government may authorize the use of a patent for medicines for its own purposes, in other words the governmental use that is aimed at solving the problems on the health issues.

Speaking about Ukraine's intention to overcome evergreen patents in the field of biomedicine, it is worth noting that the legislation of India is effective in this. Section 3 of the Indian Patents Act 1970 contains a list of objects, which are not considered the inventions. Firstly, before the amendment in 2005, that section excluded the possibility of obtaining a patent for new uses of existing substances. Secondly, Section 3 states that the discovery of new forms of existing substances is not an invention, with the exception in the situation when the efficiency of the substance in the new forms is substantially higher than in the previously known forms. Thirdly, it is not possible to patent the impurities for drug formulations. Section 2 assumes that one of the features of an object's patentability is the technological superiority of the compared ones over the existing objects or their economic importance. In addition, the Indian Patents Act, 1970, provides that a patent may be appealed within 1 year of its issue. This demonstrates the

strong position of the Indian Patent Office in applying standards to protect public health from harmful and unjustified influence of patents (Vitaliy et al., 2016).

RECCOMENDATIONS

Despite there is no perfect form of protection for the intellectual property rights in the field of biomedicine in Ukraine, the patenting is one of the most common forms. At the same time, it is necessary to complete the patent reform that has already started in the country, in particular to provide stricter criteria for patentability of the biomedical objects and take measures to overcome evergreen patents, to explore the possibility of mixed funding for researches and developments in the field of biomedicine at the legislative level.

CONCLUSIONS

The need of the protection of the intellectual property rights in the field of biomedicine arises from the state's function of health care and accordingly the search for new medicines, treatments, medical technologies and etc. Today, there is no best way to protect the intellectual property rights in the biomedical field as patenting; it is one of the most common ones. At the same time, the percentage of patents granted in Ukraine indicates the shortcomings of patent law, which leads to the issuance of weak patents in the field of medicine and pharmacy and creates an opportunity for the monopoly of owners of patented objects. Accordingly, in order to improve the patenting mechanism in Ukraine, considering the requirements of the Association Agreement with the EU and other international intellectual property acts, Ukraine is already taking the first steps: the patentability criteria are being strengthened, the list of inventions for which a patent can be obtained is being updated, Bolar exemption is being introduced as well as the possibility to challenge the patent's application. But there remains an open discussion about public funding for the developments and researches of new drugs, treatments, technologies with subsequent patenting, and their biomedical implementation.

REFERENCES

Beall, R., Nickerson, J., Kaplan, W., & Attaran, A. (2016). Is patent ever greening Restricting access to medicine/device combination products? *PLoS One, 11*(2), 1-11.

Ellen't, H. (2016). Private patents and public health. *Changing intellectual property rules to access to medicines.* Retrieved from http://accesstomedicines.org/wp-content/uploads/private-patents-and-public-health.pdf

Franjić, S. (2017). Patent in biomedicine. *Journal of Clinical Trials Pat, 2*(1), 1-6.

Gubby, H. (2019). *Is the patent system a barrier to inclusive prosperity? The biomedical perspective.* Retrieved from https://doi.org/10.1111/1758-5899.12730

Joris, J., Heus, I., Elmar, S., Pauw, I., Leloux, M., Morpurgo, M., Hamblin, M.R., & Heger, M. (2017). Importance of intellectual property generated by biomedical research at universities and academic hospitals. *Journal of Clinical and Translational Research, 3*(2), 250–259.

Kashyntseva, O. (2018). Quo vadis Ukrainian patent reform in the frame of EU-Ukraine association agreement. *Social and Legal Sciences, 1*(2), 29–40.

Kshitij, K.S. (2014). Intellectual property protection in bioinformatics and open bio development. *Asian Biotechnology and Development Review, 16*(3), 25-45.

Kulish, A.N., Harust, Y.V., Reznik, O.N., & Utkina, M.S. (2016). Implementation and administrative framework of the inclusive education in the context of the European integration process. *Journal of Advanced Research in Law and Economics, 7*(6), 1405-1417.

Law of Ukraine. (2015). *On scientific and technical activities.* Retrieved from https://zakon.rada.gov.ua/laws/show/848-19

Ministry of Public Health. (2016). *Welfare and sport, the Netherlands*. Retrieved from https://www.government.nl/documents/reports/2016/02/26/summary-of-medicinesplan

Pollack, A. (2015). *Drug goes from $13.50 a tablet to $750, overnight, the New York Times.* B1of the New York edition.

Pyatchanyna, T., Ogorodnyk, A., & Melnik-Melnikov, P. (2019). Methodological approaches to patent research in the field of biomedical sciences. *Medical Perspectives, 24*(2), 4-9.

Reznik, O.M., Volik, V.V., & Bezpalova, O.I. (2019). Approaches to education reform for children with special needs worldwide. *Asia Life Sciences, 2*(1), 447–460.

Suchita, M., & Yogmaya, V. (2017). Indian medical device sector: Insights from patent filing trends. *BMJ Innovations, 3*(3), 167-175.

Vitaliy, M.P., Iryna, A.G., & Andrii, A.O. (2016). The impact of the legal regime of intellectual property protection in the pharmaceutical market. *Wiadomości Lekarskie*, *69*(3), 582-586.