

Research Article

Criminal and Legal Protection of the Right of Intellectual Property on Medicines: Problems of Judicial Protection

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ABSTRACT:

The socio-economic, political and legal situation of Ukraine is burdened by a military-armed conflict, a regime of martial law in its certain regions, and in general, it intensifies the actualization of the protective function of the state in all spheres of vital activity of society, and especially in the sphere of ensuring the human right to life and health. The heart of modern state policy of Ukraine is based on the European and international vector of state development, its main institutions, including legal ones, which are reflected in the strategies, concepts, programs of development and covered by the reforms that are carried out in our country. The prerequisites for economical, political and social stability in our country today is the guarantee of economic security of the state, and on of its directions is the ensuring of criminal protection of intellectual property, whose objects, through their profitability, attract the attention of the criminal world and become the object of criminal encroachment. The competitive environment that is characteristic of a market economy is therefore an urgent need for the security and protection of intellectual property rights for medicines as a vital object of intellectual property right that ensures the fundamental human right to life and health.

Key words: medicines, intellectual property rights, criminal law protection, The High Court of Intellectual property.

[I] INTRODUCTION

The high level of criminal law protection of intellectual property rights and ensuring the real mechanism of its implementation is one indicator of the level of democratic and legal development of the state. Having selected the European vector of development, Ukraine has joined practically all conventions and agreements that regulate legal relations in the field of intellectual property rights, which, in turn, have become directly applicable

in accordance with the legislation of Ukraine. However, at the same time, national law plays an important role, which, unfortunately, contains a lot of gaps and conflicts in its legal regulation in terms of intellectual property law. Criminal law protection of intellectual property rights for medicines has a dual nature of the combination of private law and public-law interests. In general, the pharmaceutical industry is one of the most controversial, causing scientific and practical interest to this industry. It is precisely

because of the public health provisions, the sphere of regulation of intellectual property rights for medicines is significantly interfered by the state to achieve a balance between the interests of medicines consumers and pharmacists.

Analysis of publications. In recent years, as the result of the focus on the issue of ensuring the protection of intellectual property rights for medicines, legal science is also in search of the theoretical basis for the proposed reforms in the field of health, including the science of criminal law. In the scientific developments of criminal law, more and more attention is focused on objects of intellectual property rights, which necessitates research of some of them, including medicines. A substantial contribution in this context has been made by such domestic scientists as I.V. Venediktova, Yu.A. Dorokhina, Yu.O. Kulchinskaya, V.B. Kharchenko and others.

Formulation of research goals. The need to eliminate the gaps in the current legislation of Ukraine regarding the criminal law protection of intellectual property rights for medicines, improvement of legal regulation in this area, in order to achieve a balance of interests of consumers of medicines and pharmacists, and the state's implementation of its protective function determines the purpose and objectives of this study.

[II] PRESENTATION OF MAIN MATERIAL

Modern trends in the science of criminal law must fully reflect the realities of social relations for timely, complete and proper level of their legal regulation. Given the dynamic nature of public relations in the field of intellectual property, their changes, the emergence of new objects, there is a need for their legal protection. The high commercial, economical, and innovative value of medicines as objects of intellectual property rights, stipulates their attractiveness for criminal offenses, which

emphasizes the need for their legal protection, including the norms of criminal law.

2.1. General issues of state regulation of the sphere of medicinal products as objects of intellectual property rights. In the science of criminal law, in the contrast to criminal law, under criminal law is understood as "the system (complex) of means (criminal legislation and criminal policy), providing protection, focusing on the fact that the analyzed relationships (taken under protection criminal law) remained, as a rule, objects of protection and as little as possible were subjected to criminal encroachments" [1, p. 2]. In our opinion, the criminal law protection of intellectual property rights for medicines is a combination of criminal law means and venues aimed at preserving such a state of social relations, under the conditions of which there is no threat of causing harm to the named legal relations, as well as the restoration of the state of legal relations, in the case of their violation and the establishment of social justice.

Today's tremendous impact on the development of the protection of intellectual property rights in the healthcare sector is being implemented by the TRIPS Agreement, which promotes fair competition and fair trade rules, including in the pharmaceutical sector as well, and sets minimum standards for the recognition and protection of intellectual property rights [2]. The use of TRIPS standards in developing countries which are non-exporters but medicines consumers is due to the establishment of the complete dependence of these states on transnational pharmaceutical giants [3, p. 130]. WTO member countries are obliged to adhere to these standards, the basic principle of which is "to grant other members not less favorable conditions for the protection of their industrial property than those granted to their own national representatives." At the same time, the Agreement harmonizes the conditions of patents for at least 20 years and provides for the issuance for the patenting in all possible areas of technology, which makes it impossible the exclusion of medicines and food products from patent protection. Therefore, any new health-related products, including vaccines, medicines,

diagnostic tools, are subject to the TRIPS patent regime.

State levers of influence consist in determining the criteria of patentability of drugs, techniques and methodologies, other objects of intellectual property in the field of health care, as well as the normative consolidation for the duration of the patent. In addition, a tangible activity of state influence is compulsory licensing, which for some extent restricts the rights of the patent holder, but stands in defense of the public interest and the rights of sick people [4]. The regulatory influence of the state on the sphere of health care in terms of providing the population with affordable and high-quality medicines and realization of the right of persons to medical care is carried out simultaneously in several directions, in particular, economical (creation of conditions for functioning of the market of medicines and medical services, increase of competitiveness of domestic products, increase in incomes and decrease of its expenses for medical aid), normative work (adoption of legislative acts regulating activity on market of medical services, access to medical care of socially vulnerable groups of population, protection of the rights of individuals in this area), administrative (introduction of health surveillance and control mechanisms) [5, p. 16]. In the context of the normative direction, the issue of the trial of criminal cases should be considered by the newly established The High Court of Intellectual Property, including those that violate the intellectual property rights of medicines

In order to somewhat reduce the negative consequences of the legal protection of the results of intellectual activity (monopolization), the law introduces restrictions on intellectual property rights, including those that refer to medicines. In the general terms, the notion of limiting exclusive rights to intellectual property is a permitted free use of the object of intellectual property rights that does not require the consent of the rightholder and is not a violation of the law provided that this does not detract from the normal use of the objects and

does not undermine the legitimate interests of the right owner [6].

In the pharmaceutical industry, the development process of a medicinal product is very costly and risky, but despite this, the industry can be called the most profitable. Therefore, in our opinion, the development of pharmaceutical industry should become one of key priorities of state regulation in Ukraine. The main objects of the intellectual property of the pharmaceutical industry are outlined legally and are subjects to state protection. The analysis of the dynamics of inventive activity in the pharmaceutical industry indicates a decrease in the number of applications, which is due to an increase in current rates of fees for the patenting of inventions and utility models up to 35 times. The inventive activity in Ukraine is low and needs stimulation from the Government. The economical safety of the pharmaceutical industry is provided mainly by licensing and patenting inventions. However, protection is needed not only by the state but also by the manufacturer, therefore, in our opinion, it would be advisable for enterprises in the pharmaceutical industry to create an effective system of protection of this category of property by improving the security services of enterprises and individual officials who have access to the information [7].

2.2. Medicines as objects of intellectual property rights: a theoretical aspect. In general, intellectual property law regulates social relations in the field of creation, use and protection of the results of intellectual, creative activity (literature, science and art, inventions, useful models, industrial designs, means of individualization, etc.).

Due to its legal nature, medicines are not an independent object of intellectual property. In accordance with the current legislation of Ukraine, medicines means any substance or combination of substances (one or more APIs and excipients) that have properties and is intended for the treating or preventing of human diseases, or any substance or combination of substances (one or several APIs and excipients) that can be used to prevent pregnancy, to restore,

correct, or modify physiological functions in humans by pharmacological, immunological or metabolic action or for the medical diagnosis [8].

Based on this understanding, the concept of a "medicine" can be viewed through the lens of different institutes of intellectual property rights: either as an object of copyright or as an object of patent law. Moreover, the original name of a medicinal product can be considered as a means of individualization - a trademark, and the designation of its manufacturer in the form of a commercial name. The Criminal Code of Ukraine on the Protection of Intellectual Property Rights has devoted Articles 176, 177, 203-1, 216 and 229, 231, 232 [9], the analysis of which allows us to determine that, provided that the medicinal products act as an object of intellectual property rights, they are the object to criminal legal protection in the context of these norms. As, Y. O. Kulchynska mentioned it appropriately, that the analysis of the Criminal Code of Ukraine in the field of intellectual property rights protection showed a lack of a unified, holistic, effective and reliable system of legal protection of intellectual property. The Government is making efforts to strengthen the protection of intellectual property rights, but so far, unfortunately, no significant results have been achieved [10, p. 77].

When considering objects of intellectual property rights as objects of criminal law protection, it is worth noting that the object of criminal law and the object of the crime are not identical. In its content, the object of criminal law protection is a broader notion than the object of the crime, the reasons for this are: a) placing certain relationship in the category of protected by criminal law does not turn any infringement of them into criminally punishable act, since only the most dangerous attack on the object is recognized under criminal law as a crime; b) the criminal law protects certain objects not only from criminal offenses which are not recognized as crimes but from those that are only dangerous encroachments (for example, an injury from the insane persons or

those who have not reached the age of criminal responsibility [11, p. 183].

In the field of health protection, the subject of intellectual property rights uses the object of legal protection by using in medical practice methods, techniques, means of treatment, diagnostics and prevention of diseases, medical devices, medical instruments, medical equipment, disease prognosis, biological research environments, modeling of pathophysiological processes, medicines, medical supplies, stamps of microorganisms, products of genetic engineering, etc. [12].

2.3. Problems of judicial protection of medicines as objects of intellectual property rights.

The high level of development of the legislative framework, which is brought to conformance with international standards, does not lead to its effective action in Ukraine due to the low effectiveness of law enforcement. The whole set of reforms in the judicial system, a significant number of changes within the framework of the procedural legislation of our state has led to collisions, gaps in the legislation that do not allow today to implement the proclaimed rights in practice, in particular in the sphere of protection of intellectual property rights. At present, the issue of legal support for the newly created the High Court of Intellectual Property, including the norms of criminal law, as well as the resolution of procedural issues to ensure the consideration of cases by the said court, including in the criminal justice system, is acute.

On issues of legal protection of intellectual property rights for medicines it is worth paying attention to the competence of the High Court of Intellectual Property, which will prosecute intellectual property rights cases, in particular:

- 1) cases in disputes regarding the rights to an invention, utility model, industrial design, trade mark (mark for goods and services), commercial name and other intellectual property rights, including the right of prior use;
- 2) cases in disputes concerning the registration, registration of intellectual property rights, invalidation, extension of validity, early

termination of patents, certificates, other acts that certify or on the basis of which such rights arise, or which violate such rights or the related law interests;

3) cases of recognition of a trademark as a well-known one;

4) cases in disputes concerning the rights of the author and related rights, including disputes concerning the collective management of property rights of the author and related rights;

5) cases in disputes regarding the conclusion, modification, termination and execution of an agreement on the disposal of intellectual property rights, commercial concessions;

6) cases in disputes arising out of relations related to protection against unfair competition in relation to: the misuse of signs or goods of another manufacturer; copy the appearance of the product; collection, disclosure and use of commercial secrets; Appeal against decisions of the Antimonopoly Committee of Ukraine on issues specified by this item [13].

In addition, in accordance with Part 4 of Art. 3 of the Commercial Procedural Code of Ukraine, the High Court for Intellectual Property shall considering the cases referred to its competence under the procedure specified by the Commercial Procedural Code of Ukraine. Which, in its turn, raises the question of considering criminal proceedings on infringement of intellectual property rights in at-trial procedure under commercial law. Case consideration in at-trial procedure under commercial law is carried out in simplified and ordinary proceedings . If we analyze under what procedure the cases on infringement of intellectual property rights, including those ,that are regarding medicines , then the literal interpretation of it is of Part 3 of Art. 12 of the Commercial Procedural Code of Ukraine, which stipulates that the simplified ordinary proceedings are intended for consideration of minor cases, cases of negligible complexity and other cases for which the rapid decision of the case is priority, it can be concluded that the High Court of Intellectual Property will consider such categories of cases.

However, a more in-depth analysis of general and special norms of the IPC draws attention to the norms of paragraph 4, part 4 of article 247 of the Commercial Procedural Code of Ukraine concerning the order of simplified ordinary proceedings. In particular, cases in disputes concerning the protection of intellectual property rights can not be considered in such proceedings , except for cases on recovery of a monetary amount, not exceeding minimum subsistence income for a person able to work (which, according to part 7 Article 12 of the Commercial Procedural Code of Ukraine and part Article 8 (1) of the Law of Ukraine "About the State Budget of Ukraine for 2019" in 2019 amounts to UAH 192100 (UAH 1921 (1 subsistence minimum for able-bodied persons as of January 1, 2019) [14]. Consequently, any cases in disputes concerning the protection of intellectual property rights (except for one category) can not be considered in the order of simplified proceedings and these cases, it should be noted, cover all the subject-matter jurisdiction of the High Court of Intellectual Property, stipulated in clauses 1, 2, 3, 4 and 5 part 2 of Article 20 of the Commercial Procedural Code of Ukraine, since in its formulation does not limit the circle of intellectual property rights, the protection of which is discussed (not by appearance, not by content, not by subject of treatment).

As for the second category of intellectual property cases, which can not be considered by the High Court for Intellectual Property in the simplified proceeding , it is unambiguous. According to Clause 5, Clause 4 of Art. 247 of the Commercial Procedural Code of Ukraine, cases in disputes arising from the relationship related to protection however, including those regarding unfair competition , can not be considered in simplified proceeding . In view of this formulation , all cases in disputes arising out of the relations related to protection against unfair competition can not be considered in the order of simplified proceedings. And this means that the part of them, provided for in Clause 6, Part 2, Article. 20 CPC as a subject -matter jurisdiction of the High Court of Intellectual Property can not be considered in the simplified

proceedings procedure. All other cases should be considered by this court according to the rules of the ordinary proceedings

The jurisprudence on criminal proceedings in the field of intellectual property rights shows that it is the High Court for Intellectual Property in Ukraine that plays a key role - in development of sustainable criminal-legal protection of intellectual property rights in Ukraine, ensuring their equal application and formation of existing criminal provisions. However, the analysis of existing legislative norms allows to draw attention to the role played by the Supreme Court. In particular, Part 3 of Art. 25 of the Commercial Procedural Code of Ukraine stipulates that the Appellate Chamber of the High Court of Intellectual Property reviews appeals court decisions made by the High Court of Intellectual Property [13]. Basically, an appeal against the High Court decision on property issues is made to this very same Court and this same Court hears it. As for the cassation, the part 6 of Art. 37. The Law of Ukraine «About the Judiciary and Status of Judges» [15] stipulates that the Court of Cassation Economic Court refers to the structure of the Supreme Court, which necessarily establishes a separate chamber for the consideration of cases concerning the protection of intellectual property rights and cases related to antitrust and competition law. Also, Article 45 of the mentioned law provides that the cassation of a decision of the Supreme Court on intellectual property matters may also be carried out by the Grand Chamber of the Supreme Court, which, in cases determined by law, acts as a court of cassation in order to ensure the uniform application of the rules of law by cassation courts. Thus, the final jurisprudence on the Intellectual Property cases will not be shaped by the Supreme Court of Intellectual Property, but by the Supreme Court.

[III] CONCLUSIONS AND PERSPECTIVES OF FURTHER RESEARCH

This state of affairs allows us to recognize that today the issue of enforcement and judicial

protection of intellectual property rights, including in the area of criminal proceedings, has significant problems in the aspect of the practical realization of the protection of these rights. Thus, in fact, the situation has developed in such a way that there is no direct access to justice in matters of intellectual property rights protection, including such objects as medicines, because of the impossibility of functioning of the High Court of Intellectual Property. The hasty actions of the legislator on the formation of the Supreme Court on intellectual property issues as a specialized court have led to a number of problems and contradictions in current legislative norms, that have not allowed for the mentioned court to start its functioning for almost two years. Within the framework of the science of criminal law today, further active research requires the study of objects of intellectual property rights as objects of criminal-legal assistance in order to provide the proper protection of them by criminal provisions and the legal basis for the work of the High Court on intellectual property issues.

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