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REFORMING OF THE PATENT LEGISLATION IN THE HEALTH CARE SPHERE IN UKRAINE

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SUMMARY

This article studies the current state of the Ukrainian patent legislation in the field of health care. Mechanisms for its reforming are identified. Problematic issues of regulation of the legal status of intellectual property rights subjects in the health care sector are considered taking into account the necessity to ensure access to treatment as well as human rights at the highest available level of health. The implementation of international obligations in the national legislation should be realized with the aim of providing patent protection for the relevant objects, smoothing the possibility of obtaining protection of so-called weak patents, introduction of administrative procedures for the recognition of rights as invalid in order to promote innovative activity and protect the rights of population.

Key words: patent law, evergreen patents, surgical or therapeutic methods for treating a person or an animal, utility model, patent objection, exhaustion of intellectual property rights, certificate of additional protection.

РЕФОРМИРОВАНИЕ ПАТЕНТНОГО ЗАКОНОДАТЕЛЬСТВА В СФЕРЕ ЗДРАВООХРАНЕНИЯ В УКРАИНЕ

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АННОТАЦИЯ

В статье проводится исследование современного состояния патентного законодательства Украины в сфере здравоохранения и выделяются механизмы его реформирования. Проблемные вопросы регулирования правового статуса субъектов права интеллектуальной собственности в сфере здравоохранения рассматриваются с учетом необходимости обеспечения доступа к лечению, а также прав человека на наивысший из доступных уровней здоровья. Имплементация международных обязательств в национальное законодательство должна осуществляться с целью обеспечения патентной защиты соответствующих объектов, нивелирования возможности получения охраны «слабых» патентов, введения административных процедур признания недействительными прав с целью содействия инновационной деятельности и защиты прав населения.

Ключевые слова: патентное законодательство, вечнозеленые патенты, хирургические или терапевтические способы лечения человека или животного, полезная модель, патентные возражения, исчерпания прав интеллектуальной собственности, сертификат дополнительной охраны.

REZUMAT

Acest articol studiază starea actuală a legislației Ucrainei privind brevetele în domeniul asistenței medicale și identifică mecanismele de reformare a acesteia. Problemele problematice de reglementare a statutului juridic al subiecților de drepturi de proprietate intelectuală din sectorul sănătății sunt luate în considerare ținând seama de necesitatea asigurării accesului la tratament, precum și a drepturilor omului la cel mai înalt nivel posibil de sănătate. Punerea în aplicare a obligațiilor internaționale în legislația națională ar trebui pusă în aplicare în vederea asigurării protecției brevetelor instalațiilor relevante, echilibrarea posibilității de obținere a protecției brevetelor "slabe", introducerea procedurilor administrative pentru invalidarea drepturilor în scopul promovării inovației și protejării drepturilor populației.

Cuvinte cheie: legislație în domeniul brevetelor, brevete cu caracter permanent, modalități chirurgicale sau terapeutice de tratare a unei persoane sau a unui animal, model de utilitate, obiecții privind brevetele, epuizarea drepturilor de proprietate intelectuală, certificat de protecție suplimentară.

Description of problem. In connection with the entry into force of the Association Agreement between Ukraine, on the one part, and the European Union, the European Atomic Energy Community and their Member States, on the other part (hereinafter – the Association Agreement) [1], Ukraine itself undertook a commitment to reform the national legislation via implementing the relevant norms. Thus, according to Art. 158 and 219 of the Association Agreement, the parties ensure the proper and effective implementation of obligations under international agreements in the field of intellectual property, in particular the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Declaration on the TRIPS Agreement and Public Health, adopted on the 14th of November 2001 at the ministerial meeting within the framework of the WTO (the Doha Declaration).

The Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter – the TRIPS Agreement), adopted in 1994 during the Uruguay Round, marked a new stage in the regulation relations concerning intellectual property rights by defining minimum standards for the protection of intellectual property objects. The purpose of the TRIPS Agreement, in accordance with Art. 7 is that the protection and

enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. At the same time, according to Art. 1 of the TRIPS Agreement members may, but shall not be obliged to, implement in their law more extensive protection than is required by the TRIPS Agreement, provided that such protection does not contravene the provisions of the TRIPS Agreement. However, having stipulated in the legislation "more extensive protection", the country *de facto* cannot depart from the obligations assumed by itself in connection with the economic consequences for it (the principle of reciprocity).

The purpose of the article. The TRIPS Agreement was adopted to promote the effective and proper protection of intellectual property rights with the purpose to reduce distortions and obstacles in international trade. Instead, norms of law enacted according to the TRIPS Agreement became burdensome in the context of the enjoyment of other human rights, especially in the health care sphere. For that reason, it is necessary to study the Association Agreement, the TRIPS Agreement, the Doha Declaration and the domestic law in order to harmonize the enshrined legal status of subjects of intellectual property rights and human rights on the highest available level of health. The purpose of this article is to study the current patent legislation of Ukraine in the health care sphere and to single out mechanisms for reforming national legislation in order to bring it in conformity with the norms of ratified international agreements and to stimulate inventive activity in Ukraine.

The main material. The provisions of the TRIPS Agreement are not of direct force but are enforced by the members via the adoption of relevant national legislation that complies with the requirements of the TRIPS Agreement. At the same time, the TRIPS Agreement contains flexible norms that can be used by the member states. Hence, Art. 1 of the TRIPS Agreement declares that the members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice. Article 8 of the TRIPS Agreement, among the principles, defines the right of the states, in formulating or amending their laws and regulations, to adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of the TRIPS Agreement. Appropriate measures, provided that they are consistent with the provisions of the TRIPS Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Pursuant to Art. 27 of the TRIPS Agreement patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Therefore, the TRIPS Agreement grants the states the right to determine the criteria of the patentability at their own discretion, which, according to Carlos M. Correa, is one of the most important of the so-called "flexible" provisions of the TRIPS Agreement [2, 20]. The high level of patentability criteria reduces the possibility of obtaining weak and unsubstantiated patents.

According to Art. 7 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models", the invention meets the requirements of patentability provided if it is new, involves an inventive step and is industrially applicable. An invention (utility model) shall be considered as new if it is not part of the state of the art. The state of the art comprises everything made available to the pubic throughout the world before the date of filing of the application with the Office or, if the priority has been claimed, before the date of its priority. An invention shall be considered as involving an inventive step provided that it is not obvious to a person skilled in the art, i.e. an invention does not proceed obviously from the state of the art. It shall be considered to be industrially suitable if it may be used in industry or other field of activity. It worth mentioning that scientists substantiate the necessity of more strict criteria of absolute novelty and inventive level in relation to inventions in the health care sphere, raising the standard of inventive level in order to prevent the issuance of patents that are not truly innovative and stimulating further innovations [3].

Thereby, the legislation of Ukraine provides the legal protection of an invention, the object of which is, among others, the new application of a known product or process (para. 2 part 2 Art. 6 of the Law of Ukraine "On the Protection of Rights to Inventions and Utility Models"). The TRIPS Agreement does not contain the obligation of the members to protect the new application. The protection of such object of patenting leads to the existence of a phenomenon known as *evergreen patents.* In the healthcare sector this negatively affects the public's access to medicines, since the obtaining by pharmaceutical companies of new patents for already patented medicines as a result of insignificant changes (new use, form, combination, etc.) impede the ability to release generic drugs relative to the referent one. To avoid such negative consequences is possible only by amending the legislation. Such provisions were reflected in the already submitted to the public discussion Draft Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine on Improving the Legal Protection of Inventions and Utility Models" [4] (hereinafter – the Draft Law), issued on 19 the of October, 2017 by the Department of Intellectual Property of the Ministry of Economic Development and Trade of Ukraine. Thus, it is proposed to exclude from the legal protection a new dosage or any new characteristic or new use of the known medicinal product, except those that lead to a significant increase of therapeutic effectiveness of the medicinal product, which is confirmed by results of researches.

According to part 2 of Art. 27 of the TRIPS Agreements the members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. Thus, the TRIPS Agreement does not establish strict

criteria and allows the states to prohibit the issuance of a title of protection at their discretion. In its turn, Ukraine does not allow the patenting of inventions that contradict the public order, humanity and morality. However, the norms of Ukrainian legislation do not prohibit obtaining a title of protection for diagnostic, therapeutic and surgical methods of treating people or animals. Ukrainian scientists have repeatedly emphasized the need to exclude objects that are subject to the patenting of diagnostic, therapeutic and surgical methods of treating humans or animals, as well as chemicals and medicinal products [5, 9]. It should be noted that the Draft Law proposes to exclude from the legal protection surgical or therapeutic methods of treatment of humans or animals, methods of diagnostics of an organism of a human or an animal, the human organism at various stages of its formation and development.

Pursuant to part 2 of Art. 1 of the TRIPS Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of sections 1 through 7 of Part II of the TRIPS Agreement, namely, copyright and related rights, trademarks, geographical indications, industrial designs, patents, layouts-designs (topographies) of integrated circuits, and protection of undisclosed information. At the same time, domestic legislation provides legal protection, in addition to the abovementioned, also for a utility model. In accordance with the data of the World Health Organization 61 countries in the world provide protection for utility models, besides Ukraine, among them there are: Argentina, Armenia, Austria, Azerbaijan, Belarus, Canada, China, Denmark, France, Georgia, Germany, Hungary, Italy, Kazakhstan, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Slovakia, Spain, Turkey, etc. [6]. Unlike a patent for an invention, the patentability conditions for a utility model are novelty and industrial applicability. Applicants obtain a patent for the utility model on the basis of a formal examination within applicant's responsibility. Norms of Ukrainian legislation do not prohibit simultaneous application for the invention and utility model for the same product or process, and in case of refusal of obtaining the patent for the invention, applicants may obtain the patent for the utility model. In the health care sphere this situation is unacceptable, taking into account the internationally vested right of the person to the highest of available levels of health and the correspondent duty entrusted to the state to respect, protect and guarantee the provision of such right.

The imperfection of Ukrainian patent law is particularly noticeable taking into account the absence of possibility of filing patent objections before its entry into force. Although Art. 32 of the TRIPS Agreement obliges the member states only to make available an opportunity for judicial review of any decision to revoke or forfeit a patent, the researchers substantiate the necessity to entrench the right to file patent objection and introduce a mechanism for coordination of the decision on the issuance of patents for medicinal products with the office for health protection [3]. Thus, in accordance with Art. 16 and 24 of the Law of Ukraine "On the Protection of Rights to Inventions and Utility Models", unlike an application for a utility model, an application for an invention is a subject to publication, and any person has the right to review its materials, however, the right to appeal against the decision on the application to the Appellate Chamber is given only to the applicant. Third parties have the right to object only against the patent which has come into force via the suing the claim to the court. It should be noted that the Draft Law provides for the possibility of recognizing the rights to an invention and a utility model as void in an administrative procedure *(post-grant opposition),* as well as the right of any person to submit to the examination institute a motivated objection on an application within 6 months from the date of publication of the information about the application for the invention.

It should also be noted that pursuant to national procedural law, the person's right to apply to a court arises in the event of existence of a violated, unrecognized or disputed right, freedom or legitimate interest. *E.g.,* the All-Ukrainian Network of People Living with HIV / AIDS charitable organization appealed to the Kyiv Commercial Court with a claim for the voidance of the AbbVie Inc Patent No. 85564 for the invention *The hard pharmaceutical dosage form containing the HIV protease inhibitor, a method of its receiving.* It was made due to the fact that the state registration of the invention and the issuance of the patent of Ukraine were conducted in violation of the current legislation of Ukraine since the invention did not meet the requirements of patentability, namely: was not new and had no inventive step. By the decision of the Commercial Court of Kyiv dated the 3rd of June, 2017, the claim was denied in view of the absence, in the court's opinion, of a violation of the plaintiff's rights or interest protected by law [7]. At the moment the case is in the court of appeals.

One of the ways to prevent the issuance of unsubstantiated patents in the health care field is to secure the obligation to obtain a prior positive opinion of the relevant healthcare authority. Thus, in Brazil an alternative mechanism for filing objections was created through the statutory requirement to obtain the *prior consent* on granting of patents for pharmaceutical products in the Agency for the Control of the State of Health of the Population [8, p. 27].

When considering subjects of intellectual property rights in the field of health care, one of the most controversial remains issues of compulsory licensing and state use of a patent. Cases of other use without permission of an owner of rights are enshrined in Art. 31of the TRIPS Agreement. In spite of the fact that the TRIPS Agreement does not contain any restrictions concerning the grounds for application of compulsory licensing mechanisms, the legislation of Ukraine grants the right of exploitation without the permission of a patent holder "in order to ensure the health of the population, the state defense, environmental safety and other interests of society". Unlike the Ukrainian legislation, the TRIPS Agreement does not require an unjustified refusal to grant a license for the use of an invention (utility model), but only contains the necessity of making "efforts to obtain permission from the rights holder under acceptable commercial conditions". The attention should also be paid to the use of the terms "compensation" and "remuneration" when issuing a compulsory license. Thus, remuneration means a fee for the economic value of the permitted exploitation, while compensation is a broader concept and

may include compensation for the lost benefit of a patent holder or damages inflicted to a patent holder in connection with compulsory licensing. It should be noted that the possibility for the member states to use compulsory licensing mechanisms depends on the domestic law based on the TRIPS Agreement. The complexity of the procedure, the absence of legal will and the inconsistency of statutory acts make it impossible for a member state to use compulsory licensing as one of the main flexible provisions of the TRIPS Agreement.

When viewing compulsory licensing, it's also worth to dwell on the possibility of member states to use the mechanism of non-commercial exploitation of a patent in the public interest. Its essence is in a simplified procedure for obtaining, as opposed to the compulsory license, an appropriate permission on the initiative of the government without the obligation to obtain prior consent from the patent holder.

The Draft Law, taking into account the international obligations of Ukraine, proposes an introduction of the certificate of the additional protection of rights to inventions, according to which an owner of the patent for an invention, the subject matter of which is the active substance of a medicinal product, security tool of an animal, means of protection of plants, the introduction of which into civil circulation in Ukraine is authorized by the relevant competent authority, has the right to extend the term of validity of intellectual property rights to this invention for a term of not more than 5 years, as well as for 5 years and 6 months for an invention the subject matter of which is the active substance of a medicinal product and in respect of which pediatric investigation had been carried out.

Conclusions. Therefore, with regard to the current state of legal regulation of relations arising in respect to the objects of intellectual property right in the health care sphere, it is necessary to reform the patent law of Ukraine. In implementing international treaties, the national legislator should be guided primarily by the interests of national subjects of intellectual property law, taking into consideration the level of economic development, the availability of productive capacities and, in particular, the health of the population.

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