



## MODERN VALUES OF HARMONIZATION OF HUMAN RIGHTS AND INTELLECTUAL PROPERTY RIGHTS IN HEALTH CARE

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**Кашинцева О. Сучасні цінності гармонізації прав людини та прав інтелектуальної власності в сфері охорони здоров'я.**

Стаття присвячена міждисциплінарним аспектам сучасних цінностей гармонізації прав людини і прав інтелектуальної власності в сфері медицини і фармації. Необхідність пошуку балансу прав людини та прав інтелектуальної власності виникла для України відповідно до міжнародних зобов'язань. Сучасні цінності прав людини розбалансовано сучасними установками і загальними принципами права інтелектуальної власності. Очевидно, що ця проблема постала не лише перед Україною. Дисбаланс між правами з прав людини і прав інтелектуальної власності складається з двох основних частин: порушення прав людини на етапі отримання наукових результатів в галузі біомедицини та фармації, які можуть бути захищені в режимі права інтелектуальної власності; та порушення прав людини на етапі захисту об'єктів інтелектуальної власності в біомедицині та фармації.

Національна патентна реформа націлена на гармонізацію прав людини та прав інтелектуальної власності, шляхом впровадження гнучких положень Угоди ТРІПС, впровадження виключення Болар, розробка дієвих механізмів примусового ліцензування, тощо.

*Ключові слова:* права людини, інтелектуальна власність, моральні та етичні цінності, медицина, фармація

The interdisciplinary sphere of ethical values of harmonization of human rights and intellectual property rights in the health care (medicine and pharmacy) has arisen for Ukraine in accordance with international obligations. While providing this research it was determined that the ethical values of human rights are systematically misbalanced by modern attitudes and general principles of intellectual property law (hereinafter — IP Law) in the sphere of medicine and pharmacy. It became obvious that ignorance of main ethical values of public interest is not only the features of Ukrainian national IP Law

doctrine but of international IP Law doctrine as well. The misbalance between human rights and intellectual property rights has two main parts:

- (i) violations of human rights on the stage of the obtaining of the scientific results in medicine and pharmacy which could be protected in the regime of IP Law; and
- (ii) violations of human rights on the stage of protection of the intellectual property objects in medicine and pharmacy.

The biggest challenge is to determine the balance between the intellectual



property rights and human rights. We clearly understand that such balance has internal contraventions which demands absolutely new attitude to its resolve on the basis of the principle of «responsible innovation» in biomedicine and pharmacy.

Theoretical position of the research of the mentioned issues is based on the experience of the Center for Harmonization of Human Rights and IP Rights of Intellectual Property Research Institute of National Academy of Law Sciences of Ukraine (hereinafter — IP Research Institute of NALSU). The main achievement of the abovementioned Center in Ukraine is the creation of the opinion in Ukrainian scientific society that responsible innovations in the sphere of biomedicine and pharmacy are oriented not only towards competition and economic growth, but also towards values transcending an individual. The strategy of Ukrainian patent reform, in the sphere of medicine and pharmacy on the one hand has taken progressive European standards of protection of intellectual property objects in the sphere of medicine, but on the other — goes towards the rethinking of general principles of future of intellectual property doctrine on the basis of necessity of resolving of social and ethical concerns.

The Scientific Conception of Harmonization of Human Rights and IP Rights is an integral part of the National Policy of the Development of Law in Ukraine adopted in March 4, 2016 by the National Academy of Law Sciences of Ukraine. The author of the presented research is a scientific supervisor of PhD students of IP Research Institute of NALSU.

The methodology which should be used in the research of balance of human rights and intellectual property Rights is a comparative analysis of the various paradigms in ethics, deontology, philosophy of science, law and bioethics from the point of harmonization of the interests of researcher, inventor, individuals as an object of the biomedical research and public interest and its impact into the future IP Law.

And the objectives of the research are to consolidate modern morality, ethics of science and law on the basis of the secular background into the modern doctrine of IP Law in the sphere of biomedicine and pharmacy and to contribute such results into international doctrine of IP Law and bioethics. The main result of providing research could be transmuted into the new doctrine of IP Law which has to be based in the modern values of human rights.

It is possible to presume the successful cooperation between different scientific institutions which could create modern interdisciplinary paradigm of human values in IP Law.

To achieve the mentioned goal the Center for Harmonisation of Human Rights and IP Right determines the strategy which includes the following issues:

- (i) ethical justification and scientific validity of biomedical researches involving human beings (ethical responsibility in a protocol design) and the protection of the result of such research in the object of IP Law;
- (ii) the social and law-making role of ethical review committees;
- (iii) ethical review of external sponsored research including the ethics of ensuring risks and potential benefits;
- (iv) ethical and legal aspects of organization of biobanks;
- (v) ethical and psychological aspects of individual informed consent (comprehension, renewing, cultural consideration, use medical records and biological specimens collected for other purposes, wave of consent requirements, consent of vulnerable individuals);
- (vi) ethics of using identifiable and non-identifiable materials of human beings;
- (vii) ethics of researches using health-related registries (databanks of genetic, cancer registries etc.);
- (viii) ethical and moral requirements of the patentability of the intellectual property objects;



- (ix) the world experience in the field of working out of national legislation in the sphere of protection of Human Rights in biomedicine and pharmacy from the point of the principles of the main international conventions, in particular, the legislation regulating aspects of prenatal genetic researches and legal status of human embryo and public interest;
- (x) comparative analysis of the legal protection of the objects of biotechnologies (in particular human beings) as the objects of the Patent Law in EU countries, USA and Canada;
- (xi) comparative analysis of the legal protection of assessments to treatments and pharmaceuticals on the basis of avoiding the economical discrimination.

The modern Ukrainian situation, the existence of political will and international support give the big chance to reform Ukrainian patent system in the sphere of medicine and pharmacy in accordance with the highest standards of rule of human rights.

Let us pay proper attention to changes which take place in the international legal doctrine of Intellectual Property.

The World Intellectual Property Organization Committee on the Law of Patents was meeting this summer. Among the agenda items: updates to the international patent system, exceptions and limitations to patents, quality of patents, patents and health, confidentiality of client-patent advisor communications, and technology transfer. A recent developed country proposal relates to increased work-sharing among patent offices. Also on the table this week is a new proposal to study the assessment of inventive step by patent practitioners [1].

This is only the first step in the frame of EU. Regarding the least-developing countries history has deeper legal roots.

The main international document in the frame of WTO which in one hand strictly regulated intellectual property sphere and in other hand gives the liber-

al flexibilities for the least-development countries in the health care sector.

So on the one hand the TRIPS Agreement [2] sets out detailed obligations in respect of the protection of inventions, including:

- to recognize patents for inventions in all fields of technology, with limited exceptions;
- not to discriminate with respect to the availability or enjoyment of patent rights;
- to grant patent rights for at least 20 years from the date of application;
- to limit the scope of exceptions to patent rights and to grant compulsory licenses only under certain conditions;
- to effectively enforce patent rights.

But in other hand the country-members of WTO should comply with the minimum standards of the TRIPS Agreement. Moreover, they can adopt measures which are conducive to social and economic welfare (Article 7 of the TRIPS Agreement), such as those necessary to protect public health, nutrition and the public interest in sectors of vital importance for their socio-economic and technological development. Countries can also adopt measures to prevent the abuse of intellectual property rights (Article 8.1 and 8.2 of the TRIPS Agreement) [3].

The strategy of Ukrainian patent reform in the sphere of health care should be harmonized to the European Legislation, the legal protection shall not extend to such technology objects:

- therapeutic and surgical methods of treatment of humans and animals;
- methods of diagnostic and prevention of diseases that may be used for treatment of humans and animals;
- human organism on the different stages of growth and development and simple discovery of elements of a human being, for example sequence or partial sequence of the genes;
- new use of known substance;
- new forms of previously known substances such as: salts, esters, ethers, polymorphs, metabolites, isomers,



isomers mixtures, combination of known compounds and other derivative forms of previously known substances.

We also would like to use the Polish experience of modern understading of the abuse of intellectual property rights. Thus, according to Article 68 of Industrial Property Law of Poland: «Uprawniony z patentu lub z icencji nie może nadużywać swego prawa, w szczególności przez uniemożliwianie korzystania z wynalazku przez osobę trzecią, jeżeli jest ono konieczne do zaspokojenia potrzeb rynku krajowego, a zwłaszcza gdy wymaga tego interes publiczny, a wyrób jest dostępny społeczeństwu w niedostatecznej ilości lub jakości albo po nadmiernie wysokich cenach» [4].

So we shall not ignore the possibility to determine the abuse of rights deriving from the patent in medical field. The person who owns the intellectual property rights for an invention (utility model) in a medical sphere on the basis of a patent or a license agreement, has no the right to prevent third parties to use the invention (utility model) for public health protection when it leads to a violation of the human right of access treatment due to lack of medicine in Ukraine or high prices.

The dispute about the abuse of intellectual property rights shall be settled in a court on the basis of claim of any person who considers that his rights or legitimate interests affected by the abuse of intellectual property rights or the suit of the central body of executive power, which formulates and implements policies in the field of healthcare.

The dispute about the abuse of rights deriving from the patented invention in medical field as a result of the issuance of a supplementary protection certificate shall be resolved in court at the suit of any person who considers that his rights or legitimate interests affected by the abuse of intellectual property rights or the suit of the central executive body that forms and implements policy in health care.

The other important modern value of IP Law is the Bolar provision. In patent law, the research exemption is an exemption to the rights conferred by patents, which is especially relevant to medicines. According to this exemption, despite the patent rights, providing the researches and tests for preparing regulatory approval, for instance by the FDA in the United States or by the State Expert Center of Ministry of Health of Ukraine does not constitute infringement for a limited term before the expired of patent validity.

«The principle behind the Bolar exemption is that generic companies should be in a position to take the necessary preparatory measures in order to be able to enter the market without delay once patent protection expires» [5].

This exemption allows generic manufacturers to prepare generic drugs in advance of the patent expiration.

The next important mechanism to implement modern values in IP Law is to use the mechanism of compulsory licensing in *ordre public* by the legal instruments of intellectual property and anti-monopoly legislation.

Summarizing mentioned above we declare our openings for all scientific discussions regarding the experience of implementation of ethical norms and moral standards into the legislation in the sphere of harmonization of human rights and intellectual property rights, legal regulations of biomedical researches on human beings with the purpose of legitimization of such scientific results. ♦



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**Кашинцева О. Современные ценности гармонизации прав человека и прав интеллектуальной собственности в сфере здравоохранения.** Статья посвящена междисциплинарным аспектам современных ценностей гармонизации прав человека и прав интеллектуальной собственности в сфере медицины и фармации. Необходимость поиска баланса прав человека и прав интеллектуальной собственности возникла для Украины в соответствии с международными обязательствами. Современные ценности прав человека разбалансированы современными установками и общими принципами права интеллектуальной собственности. Очевидно, что данная проблема возникла не только перед Украиной. Дисбаланс между правами по правам человека и правам интеллектуальной собственности состоит из двух основных частей: нарушения прав человека на этапе получения научных результатов в области биомедицины и фармации, которые могут быть защищены в режиме права интеллектуальной собственности; и нарушения прав человека на этапе защиты объектов интеллектуальной собственности в биомедицине и фармации.

Национальная патентная реформа нацелена на гармонизацию прав человека и прав интеллектуальной собственности, путем внедрения гибких положений Соглашения ТРИПС, внедрение исключения Болар, разработка действенных механизмов принудительного лицензирования и т. д.

*Ключевые слова:* права человека, интеллектуальная собственность, моральные и этические ценности, медицина, фармация

**Kashyntseva O. Modern values of harmonization of human rights and intellectual property rights in health care.** The article is devoted to interdisciplinary aspects of modern values of harmonization of human rights and intellectual property rights in the sphere of medicine and pharmacy. The necessity to find a balance between human rights and intellectual property rights arose in Ukraine in accordance with international obligations. Modern human rights values unbalanced by modern facilities and the general principles of intellectual property rights. It is obvious that the problem arose not only for Ukraine. The imbalance between the rights of human rights and intellectual property rights consists of two main parts: the human rights violations at the stage of obtaining scientific results in biomedicine and pharmacy, which can be protected in the mode of IP rights; and human rights violations during the protection of intellectual property in biomedicine and pharmacy.

National patent reform aims to harmonize rights and intellectual property rights, by implementing flexible provisions of the TRIPS Agreement, implementation Bolar exception, development of effective mechanisms for compulsory licensing, and so on.

*Keywords:* human rights, intellectual property, moral and ethical values, medicine, pharmacy