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ETHICAL VALIDITY OF RESEARCHES ON HUMAN BEINGS AS THE OBJECTS OF PATENT LAW IN UKRAINE

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Кашинцева О. Етична легітимність біомедичних досліджень на організмі людини як об'єктів патентного права в Україні.

У статті досліджуються тенденції правового регулювання біомедичних досліджень з позиції міжнародних етичних норм і вимог моралі. Аналізується вітчизняне законодавство з позиції його імплементації у європейську правову матерію.

Актуальність теми дослідження зумовлена стрімким розвитком індустрії біомедичних досліджень. Підписання та ратифікація Україною Угоди про асоціацію між Україною та ЄС (далі — Угода про асоціацію) висуває перед українською науковою спільнотою нові виклики щодо уніфікації умов легітимізації результатів наукових досліджень у сфері біології та медицини, зокрема їх об'єктивізація у відповідні об'єкти інтелектуальної власності. Відповідно до положень Угоди про асоціацію винаходи вважаються непатентоспроможними у випадках, коли їхнє комерційне використання суперечить *ordre public* (суспільному порядку). Положення Глави 22 Розділу V Угоди також вимагають адаптації положень національного законодавства до законодавства ЄС у сфері медицини.

У статті аналізуються положення Конвенції про біомедицину. Основний принцип Конвенції про біомедицину, який визначає її дух, — це принцип домінування інтересів окремої людини над інтересами науки та суспільства в цілому. Згадана Конвенція беззаперечно встановлює пріоритет прав людини як об'єкта дослідження над правими людини як суб'єкта дослідження.

Щодо Гельсінської декларації, то Всесвітня медична асоціація (ВМА) розробила цей документи для закріплення етичних принципів медичних досліджень за участю людини як об'єкта дослідження, зокрема й дослідження на людських матеріалах *(human beings materials)* та даних, які можна ідентифікувати. Незважаючи на те, що згадана Декларація адресована передусім вченим-лікарям, ВМА заохочує й інших учасників медичних досліджень, які відбуваються за участю людини як об'єкта дослідження, дотримуватися закріплених у документі принципів.

У статті визначаються загальні принципи проведення біомедичних досліджень:

- принцип пріоритетності людського життя, здоров'я, гідності та біологічної недоторканності;
- принцип пріоритетності права особи на самовизначення, недоторканність приватного життя й конфіденційність особистої інформації об'єктів дослідження;
- принцип відповідності біомедичного досліджень національному законодавству країни проведення;
- принцип недопустимості та заперечення наукового і правового визнання результатів медикобіологічних експериментів у разі відсутності відповідного національного законодавства у країні здійснення експерименту;
- принцип чіткого визначення дизайну наукового дослідження за участю людини як об'єкта дослідження у протоколі, де дослідником чітко зазначаються задіяні етичні аспекти та вказати, як враховані принципи чинної Гельсінської декларації;
- принцип обов'язковості подання інформації про фінансування, спонсорів, інституційну належність, інші потенційні конфлікти інтересів, засоби заохочування суб'єктів та об'єктів, задіяних в дослідженні;
- принцип обов'язкового моніторингу біотичним комітетом медикобіологічного експерименту.

Ключові слова: права людини, біомедичні дослідження, інтелектуальна власність

Under European Union — Ukraine Association Agreement [1] Ukraine takes the obligations to implement the European standards of protection of Human Rights into the national legislation in general and in the sphere of Intellectual Property particularly. In present time as well as last 20 years Ukraine has provided a wide humanization of national and EU legislation in different spheres. Ukraine has joined the Council of Europe (1995) and adopted the Constitution (28.06.1996). In 1994, the Agreement on Partnership and Cooperation between Ukraine and the European Communities and their Member States was ratified, and in 2005 the Cabinet of Ministers of Ukraine and the Council on Cooperation between Ukraine and the European Union approved an action plan for advancing compatibility of legislative systems «Ukraine — European Union» (12.02.2005). Ukraine has adopted a number of international legal standards in the domains of human rights and health care, has created conditions for integration of international norms into its national legislation.

Having become a member of the European and World community, Ukraine simultaneously took a wide range of obligations, aimed at promoting integration into «world territory». The mentioned obligations flow out from the ratified by Ukraine's constituent documents of such important organizations as United Nations (UN) and its specialized bodies, in particular World Health Organization (WHO), Council of Europe (CE), World Intellectual Property Organization (WIPO) etc.

Ukraine also is a member-state of Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine [2] (Convention on Human Rights and Biomedicine) which is a part of Ukrainian national legislation. However, because of the subject matter of this paper (ethical validity of biomedical researches) it is important for us that Ukrainian Medical Association is a member of the World Medical Association which adopted Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects (Helsinki Declaration). This Declaration makes a great influence on the ethical norms which regulate the researches on human beings despite that fact that Declaration belongs to the flexible law.

According to the mentioned Convention the country-party should protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Each party shall take in its internal law the necessary measures to give effect to the provisions of this Convention. The interests and welfare of the human being shall prevail over the sole interest of society or science. Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

The Ukrainian legislation in the sphere of legal regulation of providing the biotechnological and medical (biomedical) researches on human beings has many ethical lacks that have negative influence on the criteria of patentability of them as the objects of patent law. There are widely different views about the relevance of social and ethical considerations in the assessment of patents. One view is that patents form part of an economic system for encouraging investment in research and that the patent system should be concerned primarily with assessing the inventiveness and utility of new inventions [3]. Social and ethical concerns are separate issues to be dealt with by other means [4]. It is also argued that the patent system may not be an effective mecha-

nism for dealing with social and ethical considerations because it was not designed to address such issues [5]. In 2002 the Organisation for Economic Cooperation and Development Working Party on Biotechnology Report (OECD Report) stated in its report that it was generally agreed that «in cases where fundamental ethical decisions are at stake, the debate needs to take place in society at large rather than in the patent offices, which have no special authority in moral matters» and that intellectual property law is «fashioned primarily to promote inventiveness and the disclosure of advances in technology» and it cannot be easily reformed to operate as an ethical-legal instrument of public policy at all and in the sphere of biomedical researches in particular [6]. However, it is difficult for us to accept mentioned above positions. We undoubtedly trust that the instruments of intellectual property law could be the proper mechanism for harmonization of science and morality.

According to the Ukrainian Law «On Protection of Rights on Invention and Utility Models» the legal protection shall be granted to an invention (utility model) that does not contradict the public order, humanity and morality and complies with the requirements of patentability [7].

So, Ukrainian patent system has social and ethical dimensions, which differ according to the type of invention. Actually in considering reforming of the Ukrainian patent system (as it applies to the results of biomedical researches, genetic materials and technologies) the economic dimensions of the patent system cannot be divorced from their social or ethical impact into the patent system and it also has social and ethical dimensions, which differ according to the type of invention. In Ukraine the lack of the ethical norms in national legislation in the sphere of protection of human rights in biomedical researches is a great obstacle to national biomedical researches and makes them invalid for international scientific community. Despite the fact that Ukraine is a member-state of major international legal documents in the sphere of Human Rights and protection of human beings in the field of biomedical researches, it has no proper domestic legislation with enough level of protection of individuals in such sphere.

In Ukraine there is a lack of such kind of scientific works which could be the doctrinal background which consolidate modern morality, ethics of science and law on the basis of the secular background. This problem arises in particular from the problem of the governmental financial support of such kind of researches and this gap in secular doctrine is filled by the representatives of various religious denominations which try to have influence also on the law-making procedure as well as to the social consciousness. Ukrainian scientific community could reach the success in resolving of this social and legal problem basing on the theory of «ethics of social consequences» which is established by one of the best modern scientist in the sphere of modern ethics — V. Glushman.

The ethics of social consequences is one means of satisfying non-utilitarian consequentialism. It is characterized by the principles of positive social consequences, humanity, human dignity, legality, justice, responsibility, tolerance as well as moral obligation [8]. The author together with V. Glushman accepts the idea that human society has been founded through the idea of social contract, and that its being is possible only due to that social contract performed on the international level, for example, like international cooperation in trade, health and environmental care and so on.

It is very important to accept one of the V. Glushman principles that the essential principle for the performing of a social contract is a cooperative idea for the sake of the protection of human be-

ings. It follows that one of the aims of humankind is a stable community as well as society, where the individual delegates a part of itself to rights and freedoms that benefit the social institution. That institution has the duty to protect and pursue its rights and justified interests in accordance with rights and justified interests of other concerned people.

The fulfilling of humanity, the implementation of principles of respect for human dignity in the sphere of scientific researches should be implemented into the national Ukrainian legislation on the basis of common sense morality.

The priority and absoluteness of rights is often gist for ethical debates. There are different views on the extent to which patent law itself should recognise social and ethical considerations, for example, through new criteria for patentability. One view is that social and ethical considerations are better addressed through direct regulation of the use or exploitation of patented inventions, rather than through the patent system directly. In contrast, it has been suggested that we should change the way we think of the patent system, so that patent law is seen «as a regulatory mechanism for a number of economic and social ends-including investment in innovation, access to medicine, protection of the environment, and the acknowledgment of indigenous knowledge» [9].

On the way of reforming of national patent system the experience of other countries in the sphere of implementation of ethics norm into the patent legislation should create the legal arguments to develop common attitudes.

The Patents Act of Australia does not contain an explicit mechanism to allow social and ethical considerations to be taken into account by patent examiners in assessing the patentability of a particular invention. Section 6 of the Patent Act of Australia determines that an invention should «be not contrary to the law, nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient». It is arguable that the term «generally inconvenient» includes social and ethical considerations within its scope [10]. Decisions of the High Court and the Federal Court contain *obiter dicta* suggesting that the «generally inconvenient» exception incorporates public policy considerations and may provide a basis upon which the grant of a patent could be refused [11]. It is very interesting for us that Australian courts have generally declined to rely solely upon matters of public policy or ethics under this exception in considering whether an invention is inappropriate subject matter for the grant of a patent. The courts have suggested that such issues are to determine for Parliament, not judges.

The TRIPS Agreement in Article 27(2) provides that member-states may exclude inventions from patentability if prevention of the commercial exploitation of an invention 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» [12]. The same provisions have been included in Australia and United States, Australia-United States Free Trade Agreement, 18.04.2004, Article 17.9.2(a) [13].

European law also provides an exclusion from patentability on the basis of «*ordre public* or morality» in similar terms to the TRIPS Agreement. The exclusion is set out in Article 53(a) of the European Patent Convention (EPC) [14] establishes the exceptions of patentability, beyond them are the followings: inventions the commercial exploitation of which would be contrary to «*ordre public* or morality», such exploitation should not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; plant or animal varieties or essentially biological processes for the production of plants or

animals (except microbiological processes or the products thereof); methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body (except products, in particular substances or compositions, for use in any of these methods). The issues of EPC are also implemented in European Parliament's Directive on the Legal Protection of Biological Inventions (EU Biotechnology Directive) [15]. In Article 39 of this Directive it is determined that whereas *ordre public* and morality correspond in particular to ethical or moral principles recognized in a member-state, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention.

Summarizing mentioned above we could resolved that scientific researches of human beings should be ethical valid only if they fulfill the demands which are determined in Standards and Operational Guidance For Ethics Review of Health Related Researches with Human Participants [16].

Firstly, it is a *respect for the person* who incorporates two main ethical considerations. The first one is that respect for autonomy of person, which requires that individuals those are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination. The second one is that protection of individuals with impaired or diminished autonomy which requires that those who are dependent or voluntary be afforded security against harm or abuse.

Secondly, it is *the principle of beneficence* refering to the ethical obligation to maximize benefit and to minimize harm. This principle gives rise to norms requiring that the risks of research are reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, nonmaleficence (do no harm).

Thirdly, it is *justice* refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research. The differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons; one of such distinctions is vulnerability. *Vulnerability* refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons [17].

Ukrainian Law «Principles of Ukrainian Health Care Legislation» [18] established the mentioned above principles. However, these norms have not enough level of its realization on practice in reality of research process. Despite that fact that Ukrainian legislation demands to establish the local ethics committees in every institutions providing the biomedical researches, national legislation does not determine the methods of control and responsibility for the violation of such ethical norms. We do not mean the criminal responsibility for torture,

first of all we stress that it has to be strong public control and wide circle of subjects responsible for the ethical aspects of process of biomedical researches and for the ethical aspects of its result: *e.g.* expert board of scientific journals, publishing houses etc.

Ukrainian scientific society clearly understands the necessity to harmonize the national legislation to the EU norms and standards especially in the sphere of biolaw andintellectual property law on the principles of Helsinki Declaration and Convention on Human Rights and Biomedicine.

For the achievement of such important goal it has been established the Center for Harmonization of Human Rights and Intellectual Property Rights of Intellectual Property Research Institute of National Academy of Law Sciences of Ukraine (hereinafter — the Center) [19].

Actually in Ukraine the Center has the following background for its researches:

1) the Ukrainian Governmental Program on Providing of the Biotechnological Researches in Ukraine demands the professionals with international experience in the field of legal regulation of such researches to work out the national legislation;
2) the participation of the Intellectual Property Research Institute of the National Academy of Law Sciences of Ukraine in the drafting process of national legislation in the sphere of biotechnologies, medicine and pharmacy in the following fields:
   - the obtaining, saving and using the human genetic information;
   - the protection of human rights while providing the prognostic genetic researches;
   - the implementation of ethical norms into the intellectual property law legislation (the ethical responsibility of the objects of intellectual property);
   - the protection of the human beings in the field of biotechnologies and medicine;
   - the establishing of ethical review committees and ethical responsibility of protocol designs.

The Center has the scientific priorities which are determined in the Conception of the Development of Scientific Direction: «Harmonization of Human Rights and Intellectual Property Rights in the Sphere of Medicine and Pharmacy» [20]. The main actual scientific direction of the Center's researches is «Ethical Standards and Legal Regulations for the Researches with Human Beings» which is providing from the point of analyses of ethical aspects of the priority and absoluteness of human rights in the sphere of biomedical researches and its scientific results (intellectual property objects) on the basis of social contract which will be implementing in different norms of the national legislation.

The research of the ethical aspects of biomedicine researches includes the following issues:

- ethical justification and scientific validity of biomedical researches involving human beings (ethical responsibility in a protocol design); the social and law-making role of ethical review committees;
- ethical review of external sponsored research including the ethics of ensuring risks and potential benefits;
- 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);
- ethics of using identifiable and non-identifiable materials of human beings;
- ethics of researches using health-related registries (databanks of genetic, cancer registries etc.);
- ethical and moral requirements of the patentability of the intellectual property objects.

Summarizing mentioned above we declare our openness 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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Оксана Кашинцева. Этическая важность биомедицинских исследований на организме человека как объектов патентного права в Украине. В статье анализируются тенденции развития законодательства в сфере интеллектуальной собственности сквозь призму международных этических стандартов проведения медикобиологических исследований с участием человека. Украинское законодательство рассматривается с перспективы интеграции в европейскую правовую материю.

Ключевые слова: права человека, биомедицинские исследования, интеллектуальная собственность

Kasyntseva O. Ethical validity of researches on human beings as the objects of patent law in Ukraine. The article analyzes the development trend of legislation in the field of intellectual property through the prism of international ethical standards for biomedical research involving human being. Ukrainian legislation is considered from the perspective of integration into the European legal matter.

Keywords: human rights, biomedical researches, intellectual property