Limits of Interference into the Human Genome

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KEYWORDS

biomedical technologies, human genome, personal non-property rights, genome editing, health care, medical services

ABSTRACT

Introduction: The use of advances in genomics in practical medicine can positively affect the quality of services in the healthcare sector, as well as the results of applied medical research.

Objectives: The purpose of the article is to research regulatory and scientific approaches to the concept of the human genome as an object of legal relations, as well as to determine the limits of interference into a human being's genomic integrity.

Materials and methods: Regarding the chosen subject matter of research, the author while preparing the scientific article has used materials of international regulatory legal acts, Ukrainian and foreign legal literature. To achieve the set aim, the author has used general scientific and special methods of scientific cognition. These methods combined with the scientific principles of objectivity, scientificity and reasonableness, have provided a comprehensive research of the limits of interference into the human genome.

Results: The concept of the human genome, as well as its material and non-material components, have been studied from a biological and legal point of view. The private and legal nature of the human genome as a personal non-property good has been defined. The concept of the individual's integrity, enshrined in international regulatory legal acts, has been analyzed from the point of view of its coverage of a human being's genomic integrity. It has been established that a violation of genomic integrity is possible both by the intentional actions of third parties and as a result of genome changes due to the action of natural factors. The concepts and types of the human genome editing have been defined. The potential reasons for banning the editing of human germline cells have been critically analyzed. The legal nature of interference into the human genome from the point of view of eugenical practices has been studied. The author has studied the possibility of classifying the use of vaccines on the mRNA platform as interferences into the human genome.

Conclusions: It has been concluded that there is a need to recognize the human genome as a personal non-property good, and, accordingly, as an object of private rights. The author has stated own point of view on the inadmissibility of arbitrary interference into human genomic integrity and the existing types of interference into the human genome.

1. Introduction

The development of biomedical technologies in the field of genetics and genomics has led to the emergence of fast, highly efficient and inexpensive methods of DNA research aimed at studying the human genome by reading DNA sequences. The information obtained by scientists as a result of sequencing the human genome opened up new opportunities for improving personalized medicine, as well as contributed to increasing the effectiveness of preventing serious hereditary diseases. Accordingly, the use of advances in genomics in practical medicine can positively affect the quality of services in the healthcare sector, as well as the results of applied medical research.

Since the human genome is an integral part of its biological nature, and the emergence of an artificial

possibility to influence the human genome creates the need for its effective protection, this article will be focused on the private legal nature of the genome. Most of international regulatory legal acts aimed at regulating relations related to the use of genomics achievements emphasize the universal value of the human genome, but at the same time recognize that the interests of a person prevail over the interests of society and the benefits of scientific research. This approach indicates a fair recognition of the human genome as a part of the private sphere of human life, which allows considering it as a category of private law.

Therefore, the solution of the problem regarding the possibility and expediency of assigning the human genome to the objects of rights, as well as the mechanism of its protection against unjustified interferences, is currently of great importance.

Objectives

The purpose of the article is to research regulatory and scientific approaches to the concept of the human genome as an object of legal relations, as well as to determine the limits of interference into a human being's genomic integrity.

Literature review

Given the actualization of the problem of determining the place of the human genome in the system of rights' objects, as well as the expansion of its editing possibilities, more and more scholars have been recently paid their attention for research in this area.

In particular, M. Almeida, R. Ranisch [1] in their scientific work consider the pragmatic, socio-political and categorical arguments given in the support or against new genome editing technologies and their impact on the debate about the admissibility or inadmissibility of interferences into hereditary editing of the human genome in the future. R. Yotova [2] critically evaluated the role of international regulatory legal acts in the field of human rights in regulating the use of genome editing technology, and focused considerable attention on the issue of genetic improvement of the human germline and the balance of private and public interests in the context of the benefits of such a technology for some individuals and threats of negative consequences for humanity in the whole. D. Krekora-Zając studied the issue of establishing clear legal principles of compensatory liability for damage caused by gene editing of human embryos and reproductive cells [3]. P. Enriquez, considering the issue of editing the human genome, drew attention to the relationship between embryonic genomic integrity and parental autonomy regarding made decisions on behalf of children [4]. Sh. Liu also studied the potential consequences of genome editing on healthy human embryos in the form of irreversible mutations and serious consequences for the heritability of future generations, which allowed stating the thoughts on the need for forming a comprehensive set of laws, regulations and guidelines to punish genome editing-related behavior [5]. O. Piddubnyi et al. described and characterized the moral, ethical and legal factors that arise when using technology to correct the human genetic code for non-medical reasons [6]. V. I. Teremetskyi et al. in the research considered the processes of modification of the genetic identity of human embryos from the point of view of the peculiarities of legal protection of biotechnological medical inventions [7].

At the same time, the analysis of the scientific works of Ukrainian and foreign scholars on the issues outlined in this article gives reasons to claim that their research is mainly focused on substantiating the "pro" and "contra" positions regarding the possibility of applying the method of editing the human germline. Nevertheless, scholars are satisfied with the biological definition of the concept of "human genome", ignoring its understanding from the point of view of a legal category.

2. Methodology

The tasks set by the author before the research led to the use of general scientific and special methods of scientific cognition, including dialectical, modelling, formal and logical, comparative and legal methods. Thus, one of the key methods of this research was the dialectical method, which was

manifested in the identification and comparison of phenomena that are opposite to each other in nature. In particular, when researching the issue of genomic integrity, opposing groups of scientific views on problems related to editing the human germ line are counterposed. The use of methods of analysis and synthesis was demonstrated in studying the material and non-material component of the human genome. The system and structural method in the same way made it possible to study the internal structure of the legal phenomenon of the human genome. The formal and logical method was applied to understand the logic of law norms related to researching and editing the human genome without excessive subjectivism, which allowed us to come to a conclusion about the private and legal nature of the genome as a personal non-property good. The use of the comparative and legal method was manifested in studying and analyzing literary sources and international legal acts, which made it possible to identify gaps in the existing legal regulation. In addition, the modeling method was used in this research, since the author made suggestions for improving legal regulation of the limits of interference into the human genome, in particular, regarding the mandatory nature of voluntary informed consent of a patient for using mRNA vaccines.

3. Result and Discussion

More than 30 years have passed since the completion of one of the largest scientific projects – the Human Genome Project focused on studying the entire DNA of a selected set of organisms. As a result, deciphering the sequence of the human genome accelerated the study of its biological structure and positively influenced the implementation of personalized medicine. However, in contrast to scientific achievements in the field of biology and genomics, legal science is characterized by a certain backwardness of reaction to the emergence of new phenomena, in relation to which arise relations between the subjects of rights leading to legal uncertainty of such a category as the human genome and the limits of interference into it. Accordingly, the following considerations will be aimed at eliminating the specified imbalance.

5.1. Concept and legal regime of the human genome

Despite the development of genomics and the use of its achievements in clinical practice, the term of “human genome” still does not have a clear legal definition both at international, regional and national levels. As one can see from the provisions of the Article 1 of the Universal Declaration on the Human Genome and Human Rights dated from November 11, 1997, the human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity [8]. That is, there is a rather abstract understanding of the genome at the level of international law as the common property and common heritage of all mankind. This approach indicates that the mentioned Declaration is not about an individual, but about a species genome, common to all people and different from other existing biological species. However, such an understanding aimed at protecting the species genome is not capable of protecting the genome of a specific human being. That is the reason that it is necessary to find out what the genome is in terms of the subjective rights of the members in private legal relations.

From the point of view of biology, the human genome is contained in 23 pairs of chromosomes in a sequence of paired chemical bases that are held together in long DNA molecules present in almost all body cells [9]. At the same time, the genome is a complete set of DNA instructions that are in the cell and contains all the information necessary for the development and functioning of an individual [10]. In turn, DNA (deoxyribonucleic acid) is defined as a molecule of living organisms that contains all genetic information and transmits it from generation to generation to all descendants [11, p. 7]. At the same time, DNA molecules themselves do not perform a physical function in living cells and exist exclusively to store the information in time, accordingly, DNA is only a material carrier, where the information and instructions necessary for the creation and operation of living organisms are recorded in a digitally coded form [12]. That is, the biological approach to defining the concept of the human genome indicates two main aspects of the studied phenomenon: the material one, which is responsible for the genome’s form embodied in DNA molecules, and the immaterial one, which consists of the

information that makes up the content of the genome. The correlation of these aspects and the determination of which of them is primary relatively to another one are fundamental to the formulation of the legal nature of the human genome. Since the DNA molecule devoid of information content has no significance for the functioning of the body and is used only as a material carrier of the information, the human genome is an immaterial phenomenon, because it cannot be completely removed from the body. In turn, any biomaterial separated from the human body is a carrier of genomic information, and its loss at the biomaterial level does not lead to the death of the entire organism.

There is a question in this regard, whether it is possible to identify the human genome with medical information. H. Tereshko, studying the concept of "information related to the provision of medical care", among other things referred medical information to it, which includes a) data on the state of health, b) genetic information / data [13, p. 10]. However, the further definition of medical information indicates that it is about that data, which is stored on material carriers or displayed in electronic form. In the same way, N. Artamonova understands medical information as such information that arises in the process of providing medical care and is reflected in medical documents [14, p. 28]. Given that information is processed, ordered and structured data, presented in a meaningful context, which collectively carry a logical meaning as a result of data analysis and interpretation, the human genome cannot be equated with medical information. Furthermore, the information embodied in a human being's genome is related both to a person's current or predicted health, hereditary diseases, or phenotypic characteristics. The genome also encodes information about the origin of a person from biological parents and even about ethnological origin, as well as a person's karyotype, which allows identifying a person from among other people. Thus, the genome is not limited to medical information and is the very essence of a person.

Despite the fact that the human genome is contained in DNA molecules, it still does not have a specific material substance and is contained in the set of cells of the entire human body. That is, the human genome is a component of the human biological system at the molecular level and constitutes the intangible essence of an individual, on level with life and health. Accordingly, it can be argued that a human being's genome can be attributed to personal non-property goods of a subject of private legal relations, since it is inextricably related to a person, individualizes him, is irreplaceable for a person, and is also devoid of property content, since it cannot be evaluated in monetary terms.

5.2. Concept of human genomic integrity

The genomic integrity of a person is the next thing worth of paying attention within the scope of this scientific research. Since this concept is not enshrined at the regulatory legal level, first of all, we would like to consider whether it is covered by the already existing category of bodily (physical) integrity of an individual or needs separate recognition.

Thus, the concept of bodily integrity in the United States was confirmed and made legal precedent by the United States Supreme Court (1891) with a Ruling that held: "No right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear and unquestionable authority of law …" [15]. Bodily integrity, from this point of view, is defined as both a positive and negative freedom – as self-determination and inviolability. Bodily self-determination suggests that individuals should be free to direct and control their own bodies, while bodily inviolability suggests that individuals have the right to be free from unwanted influence. That is, the concept of bodily integrity implies a privileged attitude to one's own body – the right to determine what happens to it and, above all, how other people relate to it [15].

Later, the right to respect for one's physical (bodily), mental and moral integrity was reflected in Part 1 of the Article 5 of the American Convention on Human Rights dated from November 22, 1969 [16].

Also, the Article 1 of the Convention on Human Rights and Biomedicine (1997) states that: "Parties to this Convention shall protect human 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" [17]. At the same time, the European Court of Human Rights even before the adoption of this Convention concluded that the human right to physical and mental integrity is considered as bodily (physical) privacy [18].

The right to personal integrity is enshrined by the Article 3 of the Charter of Fundamental Rights of the European Union, which consists in the fact that everone has the right to respect for his or her physical or mental integrity [19]. In this context, the integrity of a person means a fundamental value, which consists in the fact that noone can be subjected to any unlawful or unwanted interference with his or her body and mind, and the person himself has the right to act in accordance with his desires, beliefs and needs [20, p. 23]. In the fields of medicine and biology, the following must be respected in particular: (a) the free and informed consent of the person concerned, according to the procedures laid down by law; (b) the prohibition of eugenic practices, in particular, those aiming at the selection of persons; (c) the prohibition on making the human body and its parts as such a source of financial gain; (d) the prohibition of the reproductive cloning of human beings" [19]. The mentioning of the prohibition of eugenic practices and reproductive cloning in the context of the integrity of a person indicates that it also covers genomic integrity, which involves the preservation of the unique human genome, which was formed at the embryonic stage of development at the moment of the fusion of male and female reproductive cells.

The concept of genomic integrity as a component of bodily privacy consists in the inadmissibility of any interference into a person's genome without the consent. However, it is worth considering that there are cases when the genome change occurs outside of human will. According to the Article 3 of the Universal Declaration on the Human Genome and Human Rights, "the human genome, which by its nature evolves, is subject to mutations. It contains potentialities that are expressed differently according to each individual's natural and social environment including the individual's state of health, living conditions, nutrition and education" [8]. The Nuffield Council on Bioethics has also pointed out that environmental factors can cause changes in genes that can increase susceptibility to cancer [21]. Retroviruses also have the ability to insert themselves into the human genome and, as though, become its "own" genes. Initially, the genome of these viruses is RNA, but after entering the cell, the virus builds a DNA copy (clone) from its RNA, which is integrated into the genome of a human cell [22, p. 83].

Thus, one should distinguish between the violation of the genomic integrity of a person caused by intentional actions of third parties and the change of the genome due to the action of natural factors, which are often impossible to predict in advance. In case when we talk about the violation of genomic integrity through medical interferences or experiments, such actions are possible only in terms that a person gives his voluntary and conscious consent after receiving all the necessary and objective information that provides the opportunity to get a clear idea about the consequences of interference into the human genome. However, in this case, there is a question, whether it is always possible to obtain such consent and who should provide it in case of the violation of the genomic integrity of the embryo, and whether such actions are possible at all.

5.3. Interference into the human genome

Inherited genomic variations periodically lead to a disease or predispose to a disease. It is usually due to small changes in the genome that can be passed on to future generations. However, advances in modern biomedical technologies have made it possible to edit "errors" in the genome.

Thus, one of the forms of interference into the human genome is its editing, whose definition is provided by the World Health Organization. In this case, genome editing is a method of making specific changes into the DNA of a cell or organism, which can be used to add, delete, or change of DNA in the genome. At the same time, human genome editing technologies can be used on somatic cells (non-hereditary), germ line cells (gametes and embryos) not for reproduction and germ line cells for reproduction [23].

Somatic gene therapy involves a patient's DNA modification to treat diseases caused by a genetic mutation. At the same time, the effects from editing the genome of somatic cells are limited to patients and are not inherited by their descendants, since all cells present in the body tissues are somatic, with the exception of reproductive cells [24]. Considering the fact that "medical service is characterized as a type of services, whose subject matter is the provision of medical care or the implementation of medical interference" [25, p. 83], then editing of human somatic cells is essentially a medical service provided to a patient by a medical institution. In contrast to somatic gene therapy, editing of human germline cells is aimed at changing the genome of the human embryo at its early stages, which affects all cells of the body, including reproductive ones, and thus the edited genome is transmitted to future generations [26]. Therefore, it is more appropriate to call such actions as "medical interference", since this term is used to characterize legal relations and human rights in the context of the impact on a human body by means of biomedicine [25, p. 82].

According to the Article 13 of the Convention on Human Rights and Biomedicine, "An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants" [17]. That is, it is expressly provided at the European level that somatic gene therapy exclusively for medical purpose is allowed (of course, if obtaining a voluntary, informed consent from a patient to apply such a therapy method to him / her), and editing of human germline cells is prohibited. Such a position can be explained by referring to the Instruction "Dignitas Personae", which states that "since the risks associated with any genetic manipulation are significant and not fully controlled yet, taking into account the current state of research, it is morally unacceptable to act in such a way that it could cause possible harm to descendants" [27]. That is, the ban on editing human germline cells is primarily based on the lack of reliable and verified data on the consequences of changing the genome of descendants, which can cause, besides therapeutic benefits, unpredictable mutations harmful to life and health. An example of such a situation can be the correction of both mutated copies of the gene encoding beta-globin in case of detection of a hereditary predisposition to sickle cell anemia, which releases from this disease, but removes protection against malaria due to the mutation [3].

Another reason for the prohibition of genomic editing of germline cells is the debate about the impossibility to obtain consent from a person, who does not exist yet, which may violate one of the fundamental bioethical principles of the autonomy of the will. However, this aspect can be explained by the recognized principle of parental autonomy to take decisions on behalf of children, including the provision or refusal in a consent to medical care [4]. Furthermore, what will happen to embryos created through assisted reproductive technologies, if genomic loci containing deleterious mutations that cause severe hereditary diseases are found in them? Usually they cannot be implanted into a patient's body, then there is no sense to artificially maintain the viability of such "defective" embryos, as a result of which they die. In this regard, it is a rhetorical question: whether this situation more complies with the fundamental value of human dignity than editing the genome of an embryo that contains a harmful mutation.

Besides, a comprehensive interpretation of the provisions of the Article 13 of the Convention on Human Rights and Biomedicine, as well as paragraph (b) of Part 2 of the Article 3 of the EU Charter of Fundamental Rights indicates that the modification of germline cells can be perceived by the world community as eugenical practices. However, is there really a basis for this?

If we put aside the negative historical associations with the term of "eugenics" and address to the origin of the term, we can see that it was invented by Francis Galton in 1883 to reflect the idea that the ideas of the new science on heredity should be used to improve the welfare of future people [28]. The basis of eugenical ideas are conceptions about improving the human race by freeing the human genotype from harmful hereditary traits and enriching it with genes valuable for physical and mental development. Eugenics, despite its distortion and discredit, served as a stimulus for the origin and development of human genetics and one of its sections – medical genetics [29, p. 57]. Meanwhile, the services of medical genetic counselling, pre-implantation genetic diagnosis, and prenatal screening for

such diseases as Down's syndrome or cystic fibrosis, which are currently widespread, often lead to the termination of pregnancy in order to avoid the birth of children with severe genetic disorders. As a matter of fact, it is a form of liberal eugenics characteristic for the ideology of a market society, whose subject matter of influence is not the nation's gene pool, but only the genome of an individual person [30, p. 14]. At the same time, the above-mentioned medical services, as noted by W. Veit, J. Anomaly et al., affect the composition of future populations, so they are a form of eugenical practices [31]. Nevertheless, a chance to be born mostly have only healthy embryos as a result of pre-implantation and prenatal genetic screenings, which has signs of human selection. From this point of view, editing of cells of the human germ line as eugenics, which may allow "removing" certain genes containing harmful hereditary mutations capable of causing a serious disease from the human genome. But in this case, each "edited" embryo gets the opportunity to be born healthy, which is more humane than abortion due to the discovery of severe hereditary diseases that are prohibited to be treated by editing cells of the human germ line.

At the same time, despite all the benefits of editing the human genome for therapeutic and preventive purposes, there is the need in a ban on using this technology in order of "genetic enhancement" that does not relate to the treatment of diseases. It is about creating so-called "designer babies" with desired physical and psychological characteristics (for example, phenomenal memory or increased endurance). Such a ban would avoid unjust social inequality between "normal" and "advanced" people within the framework of protecting human dignity.

Another issue that is important to study in this article is whether the usage of mRNA-based vaccines is an interference into the human genome. In particular, immunization against the coronavirus disease COVID-19 took place during 2021-2022 by using vaccines developed on the mRNA platform. It was believed at the moment of vaccination that the genome of RNA viruses could not integrate into the genome of the cells of vaccine recipients. However, a recent study of the usage of liver cancer cells has demonstrated that Pfizer/BioNTech mRNA vaccine can enter the nucleus of the vaccine's recipient cells [32]. Moreover, it has been demonstrated in mice experiments that mammalian spermatozoa are quite capable of translating exogenous mRNA into DNA, assembling this DNA into plasmids and releasing them into the local environment during fertilization, resulting that the fertilized egg absorbs these plasmids and stores them during intrauterine development, after the birth and throughout life and can even transmit them to future generations [33]. That is, there are currently no scientifically based and biologically significant reasons to assume that such a phenomenon cannot occur in the somatic cells of a person who receives a mRNA vaccine [34]. Therefore, it is possible to assume that a similar process can occur after immunization with a mRNA vaccine, which will lead to the appearance of babies with a modified genome, but the consequences of such a mutation can be unpredictable. Taking into account that the progress achieved in biotechnology and biochemistry during the last century has simplified the development and production of biological weapons, and genetic engineering in this area has the most dangerous potential [35]; that is special attention should be paid to the protection of human right to the integrity of the genome when using mRNA vaccines.

Given the above, it seems that during immunization with mRNA vaccines it is necessary to inform people about the possible consequences listing the advantages and dangers of using such vaccines, until it is scientifically proven that the genome of RNA viruses cannot integrate into the genome of the cells of vaccine recipients. It is also necessary to obtain mandatory voluntary and informed consent from the recipients both for immunization and for possible interference into the genome.

4. Conclusion and future scope

Having summarised the above, we can conclude that international regulatory legal acts refer to human specific genome, which allows distinguishing a person from other biological species. Such an approach is dictated by the scientifically proven fact that the genome of all people is identical for 99.9%. At the same time, 0.1% of the genome makes each person unique and allows identifying a person among billions of people. Accordingly, both specific and individual human genomes should be protected. In

this regard, we suggest to include the genome into the objects of private rights as a personal non-property good.

Given this, it is necessary to state that the category of "personal integrity" enshrined both in international and regional regulatory legal acts must take into account not only the physical and mental dimensions, but also the genomic one, which cannot be always protected due to bodily inviolability. At the same time, genomic integrity should also be ensured by establishing a ban on arbitrary interference into a human being's genome without the voluntary, informed and conscious consent.

Such interventions are currently a medical service, since they are aimed at healing and preventing serious hereditary diseases of a patient. At the same time, only somatic genomic therapy is permitted, which allows "cutting out" or "correcting" defective sections of DNA with harmful mutations in the somatic cells of a patient's body. However, it is prohibited to edit human germline cells, which are capable to make changes into the genome of subsequent generations. It means that "edited" embryos or embryos created from "edited" germ cells cannot be implanted into a human body with the aim of the subsequent birth of a genetically modified child, even if this technology allows avoiding a severe hereditary disease that leads to disability and even death. Such a ban is based on the insufficient level of research about the consequences of interference into the genome of human germline cells, the impossibility of obtaining consent from a person who is subjected of such a therapy treatment, as well as fears of the revival of eugenical practices aimed at artificial human selection. At the same time, existing and permitted medical services in the world for genetic counselling, testing and screening at the stage before embryo implantation within artificial insemination procedures or in the first weeks of pregnancy, which can lead to a decision to terminate a pregnancy in order to avoid the birth of a genetically sick child, which is essentially artificial selection. In this regard, it seems that the technology of the genome editing of human germline cells for medical purposes should get a chance to be used in clinical practice in the future.

Besides, interference into the human genome can occur not only through its purposeful modification during the treatment of hereditary genesis diseases, but also as a side effect while using medical drugs in other types of therapy that are not aimed at changing the genome. In this regard, it is suggested to inform patients about the potential effect of mRNA platform's drugs on their genome and to obtain additional appropriate informed consent for this.

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