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Private-law definition of the concept and legal nature of human genetic information

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Hanna Krushelnytska *

Abstract

The article explores the private law regime of human genetic information. To achieve the objective, an analysis of bibliographic sources in the field of genetic and genomic research, legal support for the circulation of genetic information and its legal protection was carried out. The document also analyses the provisions of the legislation and practice of the United States and the Member States of the European Union. General and specific methods of scientific knowledge, including dialectical methods, formal logic and comparative law, were used to solve the problems raised. The article clarifies the doctrinal and legal definitions of the concepts of "genome" and "gene" of an individual. It points out the dual nature of the human gene as a material object: a DNA molecule, and also as a unit of hereditary information that is intangible in nature. The article explores the possibility of attributing genetic information to objects of civil rights, in particular material objects, intangible movable property and the results of intellectual activity. The conclusions support the need to distinguish between the concepts of genetic information and genomics. In addition, it reviews theoretical approaches to define the concept and nature of genetic information.

Keywords: genetic information; genes and genome; privacy; personal data; private law.

* PhD in Law, Senior Lecturer of the Department of Civil Law Disciplines, National Academy of Internal Affairs, 02000, Kyiv, Ukraine. ORCID ID: https://orcid.org/0000-0001-9934-6973

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Definición de derecho privado del concepto y naturaleza jurídica de la información genética humana

Resumen

El artículo explora el régimen de derecho privado de la información genética humana. Para lograr el objetivo se realizó un análisis de fuentes bibliográficas en el campo de la investigación genética y genómica, soporte legal para la circulación de la información genética y su protección legal. El documento analiza también las disposiciones de la legislación y la práctica de los Estados Unidos y los Estados miembros de la Unión Europea. Para resolver los problemas planteados se utilizaron métodos generales y específicos del conocimiento científico, incluidos métodos dialécticos, de lógica formal y de derecho comparado. El artículo precisa las definiciones doctrinales y legales de los conceptos de «genoma» y «gen» de un individuo. Señala la naturaleza dual del gen humano como objeto material: una molécula de ADN, y también como una unidad de información hereditaria que es de naturaleza intangible. El artículo explora la posibilidad de atribuir información genética a objetos de derechos civiles, en particular objetos materiales, bienes muebles intangibles y los resultados de la actividad intelectual. En las conclusiones se fundamenta la necesidad de distinguir entre los conceptos de información genética y genómica. Además, revisa los enfoques teóricos para definir el concepto y la naturaleza de la información genética.

Palabras clave: información genética; genes y genoma; privacidad; datos personales; derecho privado.

Introduction

A quantum leap in the development of medicine, biology, genetics, and genomics has allowed scientists to solve one of nature's greatest mysteries – to decipher the human genome. Genetic engineering methods of today make it possible to interfere with human DNA by introducing specific mutations or replacing or editing some gene fragments. Moreover, in the context of the COVID-19 pandemic, thanks to continuous scientific research on human DNA and RNA, scientists have been able to create vaccines relatively quickly based on artificial messenger RNA, which uses human heritable information to produce proteins and corresponding antigens.

Currently, gene editing is rapidly emerging worldwide, and scientific research in genetic engineering is on the verge of spreading the practice of genetic "improvement" of an individual (Straiton, 2019). On the one hand, this knowledge is instrumental, making it possible to discover and

develop methods for treating existing and avoiding potential diseases that previously posed a mortal danger to entire populations.

On the other hand, insufficiently protected access to genetic information about an individual as the keys to its biological nature can lead to discrimination based on heritable genetic traits and infliction of colossal damage not only to the carrier of genetic information but also to his relatives and future descendants.

In many countries of the world, the collection, storage, and use of genetic information are carried out in the plane of public law, which is associated with the taking, processing, and storage of samples of biological material and the extraction of genetic data to search for criminals, identify corpses or missing persons. In addition, several states carry out mandatory genetic registration of specific categories of citizens, including military personnel and persons whose activities are associated with an increased risk of death or missing.

However, in this article, we are discussing the private-law nature of genetic information because most of the legal acts adopted by the international community to regulate the use of genetic information pay special attention to its confidential status and recognise that the interests of an individual prevail over the interests of society and the benefits of scientific research.

This approach indicates the recognition of genetic information as part of the private sphere of human life, which allows us to consider genetic information as a category of private law. Therefore, today it is crucial to solve the issue of the possibility and practicality of classifying genetic information as objects of civil rights and the formation of a special civil-law regime for genetic information, as well as a mechanism for its protection.

That is why the article aims to explore the private-law nature of human genetic information and the legal regulation of its collection, storage, and use through the prism of protecting the rights of the individual from whom the genetic information originates. This study has the following objectives:

- determine the concept, the legal nature of genes and the human genome, as well as their place in the system of objects of civil rights;
- analyse the legal regime of human genetic information;
- explore the mechanisms of the legal protection of human genetic information.

1. Literature review

Even though the regulation of biomedical activities in the field of genetic technologies began to take shape relatively recently, among law science research, one can already find many works devoted to the legal regime of human genetic information. This testifies to the growing relevance on a global scale of the chosen problem of the article.

Imekova and Boltanova (2020), in their studies on the place of genetic information in the system of objects of civil rights, drew attention to the fact that in order to determine the civil-law regime of genetic information, it is of fundamental importance to distinguish between genetic information and genetic data. Scientists noted that genetic information is personalised information, while genetic data is pseudonymised and characterised by a formalised form.

A slightly different approach was identified in the scientific works of Novoselova and Kolzdorf (2020), who distinguish between the concept of genetic data as personalised information about a certain individual, and genetic information as a sequence of nucleotides responsible for the manufacture of a product with a specific function or otherwise affecting the management of biological processes in the body (i.e. non-personalised data that can be specific to an unlimited number of persons).

Kwiatkowski (2020), in order to identify problems of legal regulation in the field of genetic and genomic research, analysed the jurisprudence of the European Court of Human Rights in determining the legal regime of objects of genetic and genomic research, in particular genetic information, biological materials, embryos, as well as practice regarding the search for a balance of private and public interests in determining the boundaries of the implementation of genomic and genetic research.

Kosseim *et al.* (2004) studied the general directions of legal regulation adopted at the international, regional, and national levels for the protection of genetic information. Shabani and Borry (2018) analysed the new General Data Protection Regulation (GDPR), which came into force in 2016 and repealed Directive 95/46/EC (European Union, 2016), in the context of improving the efficiency and harmonisation of personal data protection in the EU, taking into account the inclusion of genetic data in the catalogue of special categories of data (sensitive data).

Clayton *et al.* (2019), examining the legal landscape of genetic privacy, note that few legal doctrines or legislation, in general, provide adequate protection or meaningful control over the disclosure of an individual's genetic information.

In this regard, it is proposed to shift attention from attempts to control access to genetic information to the question of how this data can be used

and under what terms, given the need to find a compromise between the individual and society.

Levushkin (2019), justifying the possibility of including genes and genomes in objects of civil rights, considered the issue of the transferability of genes, genomes, and genetic constructs and the possibility of concluding various civil-law contracts with them. In addition, he proposes classifying genes and genomes as objects of intellectual property rights, providing them with patent protection and establishing appropriate legal procedures.

In general, the notion of recognising the patentability of genes and genomes (both natural and synthetic) is quite debatable among scientists. It should be noted that earlier, the position on the inadmissibility of patenting genes and genetic information prevailed. In particular, Then and Schweiger (1999) are convinced that a gene is a part of the wildlife that is a common heritage. No one invented genes; therefore, they cannot be patented.

Herrlinger (2004) points out that issuing a patent for a human gene violates public order and morality. Michelotti (2007) notes that genetic compositions are actually plagiarisms from publicly available sources (natural genes); therefore, synthetic genes should not be protected as objects of intellectual activity.

However, recently the position of scientists has changed. Beyleveld (2011) does not question that genes may be subject to patenting. However, he considers the practicality of including genes in intellectual property due to the possible risks of limiting patients' access to innovative developments in genetic technologies. Burk (2013), analysing US jurisprudence, also notes that synthetic genes, even those entirely identical to natural ones, are subject to legal protection as objects of intellectual property rights. Mokhov *et al.* (2020) substantiated that genes, in particular edited or synthesised, are objects of intellectual rights.

Novoselova and Kolzdorf (2020) detail that patenting a sequence or part of a gene as a substance is possible if certain conditions are met – the presence of a technical process and the disclosure of a novel technical function: A new route to the industrial production of a gene sequence shall be described, or a new function of the gene obtained (discovered) that allows the creation of a new medicinal product or assay (Segert, 2018; Wolf *et al.*, 2019).

Thus, in the scientific literature, one can find a variety of approaches to the definition of the concept and legal regime of such objects of civil rights as a gene, a genome, genetic information and genomic information. On this basis, conclusions about the legal regime and legal protection of genetic information are very different. In this regard, in this article, the author will unify and supplement the existing approaches in the science of private law.

2. Materials and methods

Considering the chosen subject of the research, the preparation of this scientific article used laws and regulations, court decisions, and legal literature. The subject and object of the study determined the application of the methodology of the science of civil law, since genetic information is included in the objects of civil rights in the form of personal information of an individual, intangible personal property (right to privacy), and results of intellectual activity.

The tasks set by the author for the study led to the use of general scientific and special methods of scientific knowledge, including dialectical, formal logic, and comparative law methods of analysis and synthesis.

Thus, one of the critical methods of this study was the dialectical method, which manifested itself in identifying and comparing opposite phenomena. In particular, when studying the possibility of extending the regime of objects of intellectual property rights to synthetic genes and referring anonymous and pseudonymised genetic information to personal data, competing groups of scientific views on these issues are opposed.

In addition, when applying the dialectical method, an alternative (antithesis) is put forward as opposed to the preferred point of view on the identity of the concepts of genomic and genetic information. In this regard, an idea is formed about the different legal natures of these phenomena.

The use of methods of analysis and synthesis manifested itself in the study of judicial practice in the application of legislation in the field of collection, storage, and use of genetic information in different countries, in particular, the dissemination of such information on the legal regime of personal data or intangible personal property (right to privacy).

The formal logic method was applied to understand the logic of the law regarding the use of genetic information without unnecessary subjectivity, which made it possible to conclude that genetic information is of a private-law nature.

The use of a comparative law method was manifested in the study of legal approaches of various legal systems that regulate the collection, storage, and use of human genetic information, which made it possible to identify a relatively high level of freedom of action for subjects in the field of circulation of genetic information at the international level.

The theoretical and methodological basis of the author's scientific research was the works of leading scientists and practitioners in the field of medical and intellectual law, dedicated to establishing the legal nature of the concepts of gene, genome, genetic information, and human genomic information as objects of civil rights. Considerable attention was paid to the

results of studies of the judicial practice of different legal systems, which helped to identify the main approaches to determining the private-law regime of genetic information.

Reviewing of the primary sources of national and international laws and regulations on the article's topic contributed to the author's conclusions. In total, the article reviewed thirty-seven sources. The complex methods, techniques, and means determined by the article's goals and the study's objectives helped reveal the issues outlined in the article to the maximum.

3. Results

An analysis of the sources that formed the scientific and theoretical basis of this study indicates that there are disagreements in the terms used both in the laws and regulations on the relevant topic and among scientists. Therefore, the concepts of human genetic and genomic information are equated, with which the author of this article does not agree. The Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997) states that 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.

In a symbolic sense, it is the heritage of humanity. In the scientific literature, the genome is understood as the totality of an organism's genes, while the essence is not in the number of such genes but in the combination of specific genes as an integral system of a living organism.

In turn, a gene is a unit of heritable information responsible for the formation of certain qualities in the body, and with the help of which a certain process is encoded. From a biological point of view, a gene is a specific section of DNA, a sequence of nucleotides located in a particular place on a specific chromosome and responsible for the formation of products with a specific function, such as proteins.

That is, a gene is a collection of heritable material located in a single cell of an organism and contains the biological information necessary to build and maintain the organism. Genes are present in every living organism capable of reproduction. Their purpose is to follow, from generation to generation, the instructions necessary to create and maintain the life of an organism.

At the same time, DNA molecules do not independently perform a physical function in living cells and exist solely to store information in time. DNA, like a flash drive, is only a material carrier on which the information and instructions necessary for creating and operating living organisms are recorded in a digitally coded form. In other words, a gene can be viewed

as an inseparable combination of two components: Material basis – DNA molecules as a physical basis, as well as intangible content – the information contained in genes.

Unlike genes, the material carrier of the genome is a person himself/herself (living or dead), his/her organism, excluded from civil circulation, so it seems that the human genome should be identified directly with genomic information.

Although at the conventional level, the genome is defined as the heritage of humanity, the mechanism of legal regulation of human genome research and the application of their results in practice is dominated by the dispositive method, which gives participants in biomedical activities a set of rights and obligations, creating the basis for the free development of medical science for the benefit of humanity.

Given this, in the doctrine of private law and in practice, genes and the human genome are already recognised as objects of civil law. At the same time, the issue of their belonging to one or another named object of civil law is debatable. In particular, they can be considered as special substances and (or) a particular type of information of biological origin.

Recently, the discussion of the possibility of including genes in objects of intellectual property has become increasingly popular, especially considering the first successes in working with synthetic genes generated using computer software. For example, thanks to the Human Genome Project for sequencing the human genome, it became possible to print a new genome and introduce it into a living cell based on the code obtained.

However, this approach is often criticised because synthetic genes are plagiarising publicly available sources (natural genes). Since plagiarists should not, as a general rule, have the right to claim authorship, synthetic genes should not receive legal protection as objects of intellectual activity.

Meanwhile, at the regulatory level in European legislation expressly states that a biological material may be an invention and be protected by a patent if it is produced by means of a technical process, even where the structure of that element is identical to that of a natural element. The same approach was taken in the US when, in 2013, the US Supreme Court, in the case Association for Molecular Pathology v. Myriad, concluded that complementary DNA made in laboratory glassware was patentable. Generally, the possibility of patenting human genes differs in different jurisdictions (Table 1).

Table 1. The possibility of patenting human genes in different countries' jurisdictions

Countries	Genes as an object of patenting
European Union	Genes isolated from the human body or produced by means of a technical process, even where the structure of that element is identical to that of a natural element
US	Complementary DNA, synthetic genes, human-altered DNA sequences
Australia	Synthetic or altered natural genes
South Korea	Genes, parts of genes and other biomaterials isolated from nature, regardless of the source of origin
Mexico, Argentina, Brazil	Artificially isolated natural genes modified by humans
Japan	Genes artificially isolated from their natural environment, subject to industrial feasibility

Source: authors.

Despite the debatable issue of attributing genes and the human genome to a specific type of objects of civil rights, it is necessary to agree with the need to establish a special civil-law regime for genes, which would clearly provide for the possibility or impossibility of performing specific actions (transactions) with genes as an object, as well as related to such actions, a set of rights and obligations, permissions and prohibitions of different subjects participating in the relations gene engineering.

At the same time, the civil-law regime of genes should be inextricably linked with the right to life of an individual, providing a citizen with qualified medical care and patient treatment process, since any fact of interaction between an individual (patient) and a doctor, geneticist and other medical staff, gives rise to ensuring the right to healthcare.

Taking into account the established difference in the concepts of the genome and the gene as a whole and partial, it can be concluded that genetic information can be contained in any DNA molecule and store information about a certain quality, inclination of an individual, or features of the construction of his/her body.

Genetic information can reveal traits specific to a particular person and inherent traits in members of his/her family or even wider groups. In addition, genetic information can indicate both a real-life trait of an individual and only the correctness of the fact that a trait encoded in a particular DNA molecule will appear in an individual later.

In turn, genomic information is contained in a certain set of genes uniquely combined, revealing the characteristics of a particular individual as a unique being. At the same time, thanks to the genetic information of an individual, he/she can be easily identified; that is why, from a legal point of view, it is more appropriate to use the term "genetic information", since it corresponds to the concept of "genetic data", which is used in most international and national regulations to refer to information that identifies an individual.

In its most general form, genetic information is data and information obtained from a specific material source as a result of an individual's specific activity. At the same time, thanks to an individual's genetic information, he/she can be easily identified since it contains information about the previous, current physical and mental health of an individual, blood type, and other identifying information.

The main characteristic of genetic information is the presence of information about specific fragments of DNA, which is the carrier of heritable information about the individual and serves as the source of all genetically determined traits studied during the examination of biological objects.

A specific material source of human genetic information can be any biological materials, for example, biological samples (blood, blood plasma, skin, bone cells) or even a whole human corpse. As for the special activity during which genetic information is obtained, it can be a medical examination, testing, screening, medical and scientific research, genetic and molecular assays, and other types of biomedical activities.

An analysis of the legal literature made it possible to conclude that the concept of genetic information is used to define different phenomena. In particular, genetic information is defined as the following:

- genetic data containing information about human health (personalised to some extent), access to which may be restricted;
- general non-personalised information about the structure of proteins, encoded by the sequence of nucleotides;
- the general concept of nature embedded in every cell that belongs to everyone.

At the same time, along with genetic information related directly or indirectly to a specific individual and allowing him to be identified (personalised genetic information), it is also possible to extract data that allows us to obtain information about the relatives of an individual or about a certain group of persons (non-personalised data, which most often contained in a certain information system – a database).

The International Declaration on Human Genetic Data (UNESCO, 2003) uses the term "human genetic data" to mean information about the heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis. From this definition, we can conclude that genetic data is one of the types of genetic information.

In the legal literature, there is a position that the concept of information includes both information, which is viewed as information related to a specific subject, object, fact, case, the rights to which belong to the subject of information, and data – a set of information, combined and ordered according to a certain attribute, several attributes or criteria, the rights to which, as a general rule, belong to the author of this information.

From this point of view, information about the heritable characteristics of specific individuals is more genetic information than genetic data. Such genetic information is of an individual, personal nature as relating directly or indirectly to a specific or specific person. In turn, genetic data have a sign of mass character, are non-personalised data (pseudonymised) and primarily pursue research goals, for example, to develop measures to increase life expectancy, develop technologies for screening the human gene pool, assess genetic risks, create medicinal products, and genome sequencing.

According to para. 1 of Article 16 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for medical purposes (CETS No. 203), research on a person may only be undertaken if the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection. It follows from the above that this Convention considers genetic information in the context of the personal data of an individual.

Also, in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) "genetic data" is defined as personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained (European Union, 2016).

At the same time, according to paragraph 26 of the Regulation, the principles of personal data protection do not apply to any information concerning an identified or identifiable natural person, as a result of which the processing of genetic information for statistical or research purposes is excluded from the scope of data protection, which once again confirms

the difference between genetic information as personal information of an identified person and genetic data as non-personalised information of a certain circle of persons.

Consequently, the protection and dissemination of genetic information are carried out in accordance with the legal regime of personal data in the part in which genetic information identifies a particular person, affecting the right to inviolability of his private life. Even if we proceed from the fact that pseudonymisation is the processing of personal data, genetic information is subject to protection until it is depersonalised, after which it loses the status of personal data.

However, international, regional, and national regulations do not consider that DNA is a carrier of genetic information not only about a particular person but also about his/her parents, relatives, and descendants.

In addition to its individuality, the DNA molecule is associated with another main property – heredity and the method of transmitting heritable information relating to an indefinite circle of persons. Thus, it is essential to provide for the confidentiality of genetic information not only as personal data of a particular individual but also as an identifying feature of a whole group of people connected by family ties.

It should also be noted that para. 27 of the EU Regulation states that it does not apply to the personal data of deceased persons. Member States may provide for rules regarding the processing of personal data of deceased persons.

Given the above, based on the fact that human genetic information is personal biometric data obtained from specific fragments of DNA (sometimes RNA) of a living individual or a corpse, based on which it is possible to identify an individual, determine the genetic propensities of an individual, obtained voluntarily, and in cases provided for by law, forcibly fixed in a biological sample and (or) stored in an information record, database, one can draw an unambiguous conclusion that the concept of "genetic information" is wider than the concept of "personal data".

More often, genetic information has the form of data that has been processed using computer technology. Therefore, ensuring the security of genomic information will always be associated with the operating DNA databases that generate such information and ensure its storage.

Such databases are created both to register offenders and for other purposes of identifying and establishing legal facts (search for missing persons, establishing paternity, databases for medical purposes). Such databases of genetic information operate in the USA, the United Kingdom, the countries of the Middle East and Asia. The Icelandic database generally contains the genotypes of the country's entire population.

At the same time, genetic information is closely related to the categories of "private life", "family life", "right to respect for private and family life". Even the consideration of cases by the European Court of Human Rights (ECtHR) related to genetic and genomic research takes place within the framework of the right to respect for private and family life, enshrined in Art. 8 of the 1950 Convention for the Protection of Human Rights.

In such cases, the ECtHR indicates that genetic information is personal information, the protection of which is essential for ensuring the right to respect for private life (ECtHR Decision of 4 June 2013 in the case Peruzzo and Martens v. Germany). Genetic information contains data that allows not only to identify a person but also to establish a genetic relationship between people, as well as ethnic origin, and any uncontrolled or unreasonable use of genetic information is an interference with respect for private life (ECtHR Decision of 4 December 2008 in the case S and Marper v United Kingdom).

There has also been a legal debate in the United States about whether genetic information should be considered in the context of property rights or the right to privacy. In the end, the prevailing conclusion is that genetic information should be seen as a right to privacy rather than a vested interest, since it is privacy that has a more holistic view of the individual. Even in the practice of US courts in cases related to the human genome, a special place is given to disputes related to the misuse of genetic information and discrimination.

Thus, given the value that genetic information is for an individual as a "carrier" of genetic information and members of his/her family (including future descendants), as well as the high probability of using such information by third parties in order to restrict the rights of these persons and discriminate against them, it is quite justifiably extending the legal regime of privacy to genetic information.

It is to determine the guarantees of the right to confidentiality of genomic and genetic information that the UN International Declaration on Human Genetic Data was adopted, which is designed to ensure respect for human dignity, human rights and fundamental freedoms in the collection, processing, use, and storage of human genetic and proteomic data and biological samples, from which they are derived, respectively to the requirements of equality and fairness.

This Declaration sets out the criteria by which genetic data differs from personal information and requires a special legal regime guaranteed by the state (Art. 4).

In particular, genetic data can be predictive of genetic predispositions concerning individuals; they may have a significant impact on the family, including offspring, extending over generations, and in some instances, on the whole group to which the person concerned belongs; they may contain

information the significance of which is not necessarily known at the time of the collection of the biological samples; they may have cultural significance for persons or groups.

Such provisions of the Declaration indicate that two types of objects are used in genetic and genomic research and directly relate to privacy issues – these are genetic and genomic data, as well as their source – the biomaterial itself taken from a particular person.

After all, cells, tissues, or any substance of the human body, whether a sample of skin, bone, hair, or a drop of blood, contain a relatively complete picture of who we are.

Everything from gender, eye and hair colour to predisposition to certain behaviours or risk of developing certain diseases can be in a tiny biological sample that can remain identifiable even for hundreds of years. Therefore, the legal regime of privacy should extend not only to genetic information but also to biological materials that are material carriers of genetic information.

At the same time, it should be noted that the confidentiality of personal data is a relative concept. For some, the fact that they carry a little-known gene that is not essential to the average citizen may not be as important as information about an individual's credit history or marital status. On the one hand, DNA is conceptualised as a unique identifier and a record of an individual's life in the dimensions of the past, present, and future, which gives an idea of the individual in many aspects.

This naturally leads many people to desire to control and determine who has access to genetic information about them, provide solid privacy protections, or even possess personal genetic data. On the other hand, genetic data is not limited to one person, and information about one person reveals information about his/her close and distant biological relatives. Only by studying the vast array of genetic information of many people can one understand the significance and uniqueness of individual variants.

The public nature and value of genomic and genetic information make it challenging to decide what level of control individuals should have to ensure that privacy is adequately protected. It seems that a particular individual – a carrier of genetic information is obliged to determine the limits of interference in his/her personal life and give permission to introduce his/her genetic information, which is the key to the genome of a particular person. At the same time, for the development of biology and medicine, irreversibly pseudonymised genetic information should not be subject to the legal regime of privacy.

4. Discussion

Studies have shown that there is a tendency to classify a gene, a genome, genetic information and genomic information as objects of civil law and extend the legal regime of objects of civil rights to them (Mokhov *et al*., 2020).

At the same time, there are discussions about the private law nature of genes – whether to recognise them as material objects, since they are part of the material world in the form of a DNA molecule (Novoselova and Kolzdorf, 2020; Althabhawi and Zainol, 2022), whether this is intangible personal property included in the personal data of a subject of civil law Imekova and Boltanova (2020), since the DNA molecule itself is of no particular value – what matters is the code encoded in the gene, that is, the genetic information.

Does this fact mean that a single human gene is not subject to legal protection as part of the right to privacy? To perform any manipulations with the gene, it must be separated from the human body.

That is, genes are contained in any human biological material, including saliva, urine, and hair, which in most cases, naturally separate from the body without the informed consent of a person. This means that people daily leave billions of its genes everywhere, of no value, unless a particular individual is allowed to be identified (Pormeister, 2018; Ram, 2017).

The legal nature of the human genome is also ambiguous since it does not have a specific material substance and is contained in the aggregate of cells of the entire human body; that is, the genome is the intangible essence of the individual, along with life and health. The genome is devoid of economic content, and therefore, cannot be attributed to the property.

Since the literature did not distinguish between gene and genome concepts clearly, the doctrine did not investigate the difference in the legal regime of these legal phenomena (Krajewska, 2012; Lewis *et al*., 2021).

The issue of understanding the legal nature of genomic and genetic information is also debatable. In particular, there has yet to be a consensus among scientists on whether genetic information is a separate object of civil rights or is included in other named objects. Thus, some scientists believe that genetic information is covered by such intangible personal property as the right to privacy (Borodin and Ruzanova, 2021; Blinov *et al*., 2020), while others point out that genetic data is an element of such an object of civil rights as a database Imekova and Boltanova (2020).

In addition, in connection with the development of gene editing technologies, and the creation of synthetic genes using the latest computer software, at the doctrinal level, discussions are underway about the

patentability of synthetic genes and genetic data, that is, the possibility of classifying them as objects of intellectual activity (Marchant *et al.,* 2020; Wan *et al.,* 2022).

Also promising are studies of the circle of subjects covered by the legal regime of confidentiality of genetic data, given that DNA data can be used to identify not only the person from whose biomaterial the genetic information is taken, but also his relatives and future descendants, since in the reviewed articles the specified concept was not given due attention.

Conclusions

The importance of genetic data is constantly growing due to the expansion of the possibilities of its practical use. Genetic testing, medical and biological experiments, as well as mandatory genomic registration lead to the collection, processing, and storage of large amounts of genetic information about individuals. This fact indicates the need to determine the legal nature, develop a specific legal regime, and provide adequate guarantees to effectively protect genetic information from misuse.

To achieve this, the international community develops the boundaries of regulation of these issues, which are detailed in the national legislations. However, what is shared, both at the regulatory and practical level, is that genetic information is classified as personal data subject to special protection as the most confidential data.

At the same time, it is vital to maintain a balance of private and public interests, given that genetic information is of particular value for the development of biomedical technologies in order to explore the causes of certain diseases and find ways to overcome them.

International standards for the use of genetic information suggest that the interests of an individual prevail over the interests of society, which indicates the need for developing a regulatory framework for the circulation of genetic information in the plane of private law.

In addition, particular interest and prospects are seen in developing national legislation to ensure the patentability of synthetic human genes and genetic information as a result of intellectual activity. At the same time, it is necessary to approach with particular caution the possibility of including natural human genes in objects of intellectual property rights.

Thus, given the need for legislative transformations at the national and international levels, further research will be carried out to conduct a comparative-law analysis of the relevant innovations.

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