Genomic Research in Reproduction and Biobanking: An Analysis of International Legal Approaches

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Abstract: The article examines the regulatory issues of genomic research in human reproduction and biobanking. The approaches to legal regulation at the level of international law, integration organizations, and individual states are analyzed. Based on the analysis, proposals for legal regulation are formulated. Regarding the legal regulation of genomic research in the field of biobanking, the article discusses the issue of the legal standing of biobanks, approaches to the legal regulation of biobanks in various countries, and formulates proposals for the commercial use of the results of genomic research in biobanking. The article also provides an overview of some judicial decisions that had a certain impact on forming legal regulation of genomic research in the field of biobanking and human reproduction.

Keywords: Genomic research, DNA, biobanking, commercial use of results, human rights.

INTRODUCTION

Recent years have been characterized by the extremely rapid development of technologies in genomic research, which objectively affects the field of legal regulation, including at the level of concept formulation.

Among such innovations that require interpretation in terms of the law, we should note the possibility of genome editing using CRISP-Cas9 technology, implementing mitochondrial replacement therapy methods and practical use of these methods, the so-called intracytoplasmic injection of male germ cells, the ability to examine embryos for the presence of genetic diseases, the relative prevalence of donating male germ cells, oocytes, embryos and using the appropriate cells in the assisted reproductive technologies.

These technologies affect, to a large extent, genomic research in reproduction and biobanking. This article analyzes approaches to the legal regulation of genomic research in these areas in Russian law, within the framework of the national law of European and other states, as well as in international and integration law. In addition, an analysis of approaches to the legal regulation of the commercial use of the genomic research results is provided.

LITERATURE REVIEW

A significant increase has been observed recently in publications devoted to the legal regulation of genomic research. For example, Goldberg and Lonbay (2000) touch on the topic of biotechnologies to some extent. Meanwhile, it should be emphasized that publications are primarily of a highly specialized or narrowly focused nature. Unfortunately, as a rule, there are no comprehensive studies devoted to this issue, which would fully combine both the achievements of the natural sciences and the humanities.

An overview and analysis of the relevant publications are provided in the main part devoted to examining specific issues on the topic of this article.

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METHODOLOGY

The subject of the article assumes the application of certain scientific methods for an objective and comprehensive study of such a complex and multifaceted phenomenon as the legal regulation of genomic research. Historical, comparative, normative (dogmatic), systemic, and other research methods were used to disclose the content of the research topic in more detail. Also, within the framework of the study, a synergistic method and a convergence method were used, which allow combining the advantages of natural scientific and humanitarian research methods to maximize the fulfillment of the tasks and achieve the research goals. The use of the synergistic method and the convergence method gave a positive effect since it enabled to comprehensively consider and diversify the issues related to the research topic.

RESULTS

In the authors' opinion, significant results were obtained in the course of the research, relating, in particular, to the principle of the priority of human life and health over the interests of science and society. The authors tried to answer to what extent this principle is absolute, whether the introduction of serious prohibitions and restrictions on scientific research in the field of genetics is justified, or there are grounds to develop more flexible approaches. Significant results were also obtained in determining the legal standing of the genome and information related to its decoding and processing, and in considering the issue of whether the genome is only an object of natural scientific research or, due to its characteristics, it is a more comprehensive humanitarian, including legal, phenomenon that needs establishing a special legal regime.

Following the research results, special approaches to determining the legal standing of biobanks were formulated, attention was focused on the role of international legal acts of a recommendatory nature in the formation of legal regulation of genomic research. This article analyzes the legal regulation of the relevant social relations in the Russian Federation and concludes about the state of legal regulation. The possibility of commercial use of the genomic research results is analyzed, with an emphasis on the following issues: whether there is a ban on the commercial use of such results or their use is possible without restrictions, and whether there are any standards or requirements that allow for commercial use of the research results. The article provides reviews and analysis of the most significant court cases related to the research topic.

All these issues are covered in detail in the main part of the article.

DISCUSSION

Legal Regulation in Human Reproduction

As rightly noted by several authors (Kalinichenko and Nekoteneva, 2020), legal regulation of genomic research and the implementation of its results stems from the fundamental acts on human rights. At the same time, the fundamental international acts containing provisions aimed at protecting fundamental human rights and freedoms have no norms directly focused on the regulation of the reproductive genomic research.

However, when considering cases concerning the use of some genomic technologies, including reproductive ones and their consequences, the judicial authorities assess whether such actions violate the provisions of fundamental international instruments containing norms aimed at protecting fundamental human rights and freedoms. For example, the European Court of Human Rights analyzes the provisions of Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms in cases concerning the determination of the fate of embryos obtained with the help of assisted reproductive technologies, including the possibility of using them for scientific research (European Court of Human Rights, 2015).

In more detail, the reproductive genomic research is regulated in special provisions of acts of a universal nature, directly devoted to the conduct of research and development in the field of the human genome and their implementation. Such provisions are contained in non-legally binding acts of international law, the so-called soft law acts. These documents are often directly related to the principles determined by international acts dedicated to the protection of human rights. These include The Universal Declaration on the Human Genome and Human Rights (United Nations Educational, Scientific and Cultural Organization, 1997); the International Declaration on Human Genetic Data (United Nations Educational, Scientific and Cultural Organization, 2003); the United Nations Declaration on Human Cloning (United Nations, 2005)

(adopted to develop the provisions of the Universal Declaration on the Human Genome and Human Rights).

For example, regarding the implementation of the embryo genome editing, Art. 13 of the Convention for the Protection of Human Rights and Dignity of the Human Being concerning the Application of Biology and Medicine (also known as the Oviedo Convention) (Council of Europe, 1997) states that interference with the human genome aimed at modifying it can be carried out only for preventive, therapeutic or diagnostic purposes and only provided that such intervention is not aimed at changing the genome of the heirs of a given person. The risks of using genomic technologies, the consequences of which are impossible to be predicted today or in the foreseeable future, can be named one of the reasons for the introduction of such a limitation.

The preamble to the Universal Declaration on the Human Genome and Human Rights establishes the need to respect the dignity of the human person, equality, and mutual respect for people. This implies the right of all persons to respect for their dignity and their rights, regardless of their genetic characteristics, while the human personality cannot be reduced to their genetic characteristics, and requires respect for their uniqueness and originality. To ensure the priority protection of human rights and interests, it is enshrined (Article 5) that genomic research and the diagnostics or treatment based on this research can be carried out only after a comprehensive preliminary assessment of the potential dangers, risks, and benefits associated with them, taking into account all other regulations, established by national legislation. Article 10 enshrines the provisions that genomic research should not prevail over the respect for human rights, fundamental freedoms and humiliate the human dignity of individuals or groups, etc.

A significant contribution in this area belongs to such international intergovernmental organizations as the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO), and the European Union and the Council of Europe at the regional level.

In February 2019, the World Health Organization decided to convene the Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (Pribitkov, 2019) to settle the scientific, ethical, social and legal challenges associated with human genome editing, and to ensure proper assessment of risk and benefit. A study by the Chinese biophysicist He Jiankui was the occasion for this convening; his research resulted in the birth of twin girls, conceived by *in vitro* fertilization, whose DNA was altered using the CRISPR/Cas9 method to form immunity in children to the HIV, which was carried by their father. As a result, there was a split in the scientific community, scholars who had made a significant contribution to the development of this technology, called for a moratorium on human genome editing in clinical practice for a five-year period (Lander, Baylis, Zhang, Charpentier, Berg, Bourgain, Friedrich, Joung, Li, Liu, Naldini, Nie, Qiu, Schoene-Seifert, Shao, Terry, Wei, and Winnacker, 2019). (This moratorium does not apply to the embryo genome editing for research purposes, provided that the embryo is not implanted in the uterus, and to the genome editing in human somatic cells for the treatment of diseases).

The position of the United Nations Educational, Scientific, and Cultural Organization, according to which the human genome is attributed to the common heritage of humanity, is implemented in the principle of preserving the human genome as a special species and means that it is inadmissible to change the human genome.

Article 10 of the Universal Declaration on the Human Genome and Human Rights stipulates that “no research or research applications concerning the human genome, in particular in the fields of biology, genetics, and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people” (United Nations Educational, Scientific and Cultural Organization, 1997).

In our opinion, the opposition of human life and health, on the one hand, and the interests of science and society, on the other hand, leads to a negative effect in any case, no matter what interests are put at the forefront. In this regard, it makes no sense to determine which interests are more prioritized – those of a particular person or science in general. It is necessary to define and find a balance between these interests. Only a balanced approach will help avoid numerous negative situations.

At the regional level, the CoE Convention (Council of Europe, 1997) (and Additional Protocols thereto, including the Additional Protocol on the Prohibition of

Cloning Human Beings (Council of Europe, 1998)). The right to interpret the provisions of the Convention is vested, under Article 29, in the ECHR. For example, Article 16 of the Convention establishes the conditions under which research on humans is allowed. These conditions include the lack of alternative methods of comparable effectiveness to research on humans; the risks which may be incurred by that person are not disproportionate to the potential benefits of the research; the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability; the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection; the necessary consent has been given expressly and specifically with the possibility to withdraw this consent freely at any time.

In the European Union, to date, a significant number of acts have been developed that affect, to one degree or another, the regulation of reproductive genomic research.

Directive 98/79/EC on *in vitro* diagnostic medical devices (including blood and tissue donations, derived from the human body) states that "the removal, collection, and use of tissues, cells, and substances of human origin shall be governed, in terms of ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being concerning the application of biology and medicine and by any Member States regulations on this matter".

The Directive "on human tissues and cells" (The European Parliament and the Council of the European Union, 2004) establishes a number of requirements for setting standards of quality and safety for the donation, control, procurement, testing, processing, preservation, storage, distribution, and transportation of biological material between borders, especially if such actions are associated with legal restrictions that exist in the Member States.

Some aspects of the regulation of reproductive technologies when implementing genomic research are described in Directive No. 98/44/EC of the European Parliament and the Council of the European Union "On the Legal Protection of Biotechnological Inventions (European Parliament and the Council of the European Union, 1998)". Its provisions are aimed at protecting the dignity and integrity of the human individual, and therefore the human body and its elements in a natural state are not patentable, however, inventions based on elements isolated from the human body may be patentable. This Directive establishes an indicative list of non-patentable inventions, which, in particular, include processes that change the genetic identity of a person, contained in the human germline.

There is a similar provision in the Russian legislation (Article 1349 of the Civil Code of the Russian Federation). European patents are not granted for inventions or publications where their commercial exploitation is contrary to public order and morality.

The EU Court of Justice, in its judgment in the case *Oliver Brüstle v. Greenpeace eV* (European Court Reports, 2011) ruled that any cell derived from a human embryo can develop into a human being (any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilized human ovum whose division and further development have been stimulated), and is unpatentable. In addition, the ECJ also ruled that the use of such a cell for research does not make it patentable. Such an invention will also be unpatentable, including in cases where it requires the destruction of human embryos or their use as base material (Tkachuk, 2019).

Also, genomic research is considered in the legal acts of such European integration structures as the EFTA and the EEA. It is worth noting Protocol 31 to the EEA Agreement "On cooperation in specific fields outside the four freedoms" (European Free Trade Association, 2020). Article 1 of the said Protocol stipulates that since January 1, 1994, the EFTA States shall participate in the implementation of the Framework Program of Community activities in the field of research and technological development through participation in its specific programs.

Also, in terms of genomic research, the Resolutions and Recommendations of the 30th meeting of the Joint Parliamentary Committee deserve attention (European Parliament, 2008). The Joint Parliamentary Committee of the European Economic Area points out the significance of new technologies, including genomic research.

Similarly, as at the international level, there are different approaches to the genome and all information

related to its decoding and subsequent processing in national law. Several countries can be distinguished where the genome is perceived as an object of research. In some states, the genome is positioned as the common heritage of humanity and, based on these characteristics, the regulation of genomic research is built according to various schemes.

Some states use strict regulation, in which the legislation establishes bans on some types of genomic research or significant restrictions on the other. In other states, on the contrary, minimum government regulation or self-regulation of genomic research is enshrined.

Often, in states with a rigid system of regulation, one can trace the tendency to elevate the public interest above the rights and freedoms of the individual.

At the national level, two established approaches to the regulation of genomic research can be noted. The first implies the development and adoption of laws governing certain fields of genomic research. The second involves the preparation of more flexible and, therefore, largely dynamic, instructions, guidelines, and rules governing the research implementation.

In some states, biosafety laws contain provisions governing this field. Also, it is often necessary to obtain a special permit (license) to research in the field under consideration and (or) to implement their results in practice. For example, in the Netherlands, the Special Medical Procedures Act (Wet op bijzondere medische verrichtingen, 1997), which governs the provision of clinical genetic services, enshrines that a medical center providing such services must have a special permit from the Dutch Ministry of Health. It can also be noted that acts of national law, for the most part, are aimed either at exercising control, in one form or another, over the products of genetic research or at ensuring the safety of such research.

For example, laws on biological safety were adopted in Brazil, Kenya, and several other states. Brazilian Biosafety Law (Presidência da República, 2005) No. 11 105 of March 24, 2005, contains general rules for the conduct of biotechnology research, regulates constitutional principles, and establishes safety standards and mechanisms for monitoring genomic research activities, their results, and side products. The guidelines used to develop this law were recognition of scientific advances in biosafety and biotechnology; protection of human life, human health, and health of animals and plants; and adherence to the precautionary principle to protect the environment. According to the Biosafety Law, in Brazil, any trials on human embryos that have been cryopreserved and stored for more than 3 years are allowed and any experiments related to human cloning are prohibited.

Some states concerned about the demographic situation are using a more flexible regulatory system. Thus, in Singapore, Japan, and some other states, instructions have been developed to regulate relations in this field. Following the Directive of the Ministry of Health of Singapore, assisted reproductive technologies are prohibited for non-medical purposes, used only for the treatment of married couples; any methods used for sex selection are prohibited. Research on human embryos must be approved by the Ministry of Health of Singapore (Ministry of Health, 2006).

In Japan, there is an instruction “on carrying out genetic testing”, the risk of transmitting a severe genetic disease to the fetus is the criterion for the need for prenatal diagnosis. In addition, the sex of the fetus can only be disclosed if severe X-linked diseases are prenatally diagnosed. It is necessary to obtain permission for prenatal diagnostics from the Japanese Society of Obstetrics and Gynecology on an individual basis. Embryo sex selection is strictly prohibited, except for the risk of having an X-linked disease (The Japan Society of Human Genetics, Council Committee of Ethics, Matsuda, Niikawa, Sato, Suzumori, Fukushima, Fujiki, Kanazawa, Nakamura, Yonemoto, and Nakagome, 2001).

In some states of the Middle East region, in which the regulation of legal relations is based on the norms of religious law (in particular, Islamic law – Sharia) and in the field of genomic research and ensuring their safety, compliance with religious dogmas is at the forefront.

On the one hand, most of the states in this region are parties to the fundamental international instruments governing genomic research and issues related to them. On the other hand, an independent concept for the genomic research regulation is developed by the legislation of the United Arab Emirates, Qatar, Saudi Arabia, Tunisia, and other states, in particular, concerning the requirements of Islamic law. Since many modern relations are not regulated by the foundations of Islamic law, theological centers of Islamic jurisprudence (Murtazin, 2003), which interpret the Koran, play a special role.

Reputable theologians and legal scholars present oral and written judgments (fatwas) adopted on issues of current life, and the interpretation of various provisions of a general nature contained in the main sources of law. The aspects of the gene research application in medicine are of particular importance for this region, especially, those related to the diagnosis and treatment of hereditary diseases (including those that have become widespread in connection with the existing practice of consanguineous marriages).

According to most religious leaders, it is allowed to use a number of reproductive technologies, but only if ovum and sperm derived from spouses were used to obtain an embryo.

Legal Regulation in Biobanking

The history of legal regulation in global biobanking dates back more than one and a half decades. Over this time, several concepts for regulating biobanking issues have developed at the national level; some international acts have also been adopted in this area.

Thus, Finland, Sweden, Estonia, and Iceland have adopted narrowly specialized laws regulating biobanking issues. In other countries, like Israel, Spain, Hungary, laws have been passed that regulate both biobanking and closely related allied issues, such as genetic research. There are no specific laws on biobanking in the UK, USA, France, China, and Russia, however, there are separate legal norms related to biobanking issues and incorporated into broader regulations concerning public health issues, information protection, non-discrimination, etc.

In this group, one can see a fairly wide range of approaches related to the regulation level: on its one conditional edge, there are countries in which regulation of the issues under study, albeit fragmentarily, takes place at the legislative level, for example, in France (Rial-Sebbag and Pigeon, 2015), on the other edge we can see China, where issues related to biobanking are today regulated exclusively at the subordinate level, although draft legislative regulation acts are being discussed (Chen, Chan, and Joly, 2015). Many countries combine approaches – they have separate norms at the legislative level and some regulation at the subordinate level.

Legal Standing of Biobanks

There is some ambiguity in the issue about the legal standing of the biobank. On the one hand, a biobank is understood as a collection of biological materials derived from several donors for medical, research, and other legitimate purposes (as stated in part two of Section I of the Swedish Biobanks in Health Care Act) (Ministry of Health and Social Affairs, Sweden, 2002). On the other hand, a biobank is understood as a specialized organization acting under a permit (license) and the direct control of state bodies, for scientific and medical purposes. Laws adopted in some European countries establish special rules regarding the establishment of biobanks (parts three and six of the Finnish Biobank Act), the rights and obligations of biobanks (part five of the Finnish Biobank Act) (Ministry of Social Affairs and Health, Finland, 2012). Thus, biobanks are understood today as legal entities, and such understanding makes it possible to apply certain requirements for their organization and functioning, resulting in liabilities introduced in case of violation thereof.

Such a shift in approaches – from an object to a subject – seems to be quite justified, as biobanks operate in a very sensitive area related to both the rights of individuals and national security. Indeed, biobanks are obliged to ensure the safety of biological materials and the reliability of the research conclusions, and also to obtain informed consent from the donor, providing the confidentiality of information, non-discrimination, etc. The state is obliged to guarantee that the biobank complies with all these conditions – and that is why, it introduces strict criteria for licensing, reporting, and responsibility of biobanks everywhere, when regulating the issues of biobanks' activities. Concurrently, the biobank laws in most Nordic countries clearly state that, when receiving a national license or other permission, biobanks shall comply with the laws and other regulations of the state in which they received the license or other permission (for example, section II of the Swedish Biobanks in Medical Care Act, parts three and six of the Finnish Biobank Act, section four of the Icelandic Biobanks Act). Additionally, in Sweden, for example, the National Board of Health and Welfare maintains the National Biobank Register, has the right to inspect biobanks (part four of section six of the Act), and if a biobank violates the requirements of the law, it is subject to deletion from the Register (part nine of section IV of the Act). Moreover, Article 5 of the Icelandic Act, among other things, expressly stipulates that the biobank shall be located in Iceland (Ministry of Welfare, 2014). In Estonia, by virtue of the direct instruction of the law (paragraph 3), the University of Tartu was directly

appointed as the Chief Operator of the Gene Bank, whose purpose in this capacity is 1) to promote the development of genetic research; 2) collect information about the health of the Estonian population and genetic information about the Estonian population; 3) use the results of genetic research to improve public health (Riigi Teataja, 2001).

International Legal Regulation in the Field of Biobanking

Currently, there are no international treaties directly devoted to biobanking issues. At the same time, some international acts of a recommendatory nature contain provisions that are essential for the formation of mechanisms for the legal regulation of biobanking issues.

Thus, the 2003 UNESCO International Declaration on Human Genetic Data (United Nations Educational, Scientific and Cultural Organization, 2003) introduces an important division of genetic data: separable from the person from whom they were derived, depersonalized (in the 2016 Council of Europe Recommendations these data are designated as non-identifiable), and inseparable (identifiable). According to the Declaration, it is more preferable to operate with depersonalized data; however, for medical and scientific purposes, when it is justified by the needs of such research, the data can remain inseparable from the person who can be identified as their source only if it is necessary for the research.

Article 17 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes establishes the principle that biological samples are used and stored in such conditions as to ensure their security and the confidentiality of the information which can be obtained therefrom.

Article 4 of the 2003 UNESCO International Declaration (United Nations Educational, Scientific and Cultural Organization, 2003) requires states to give due consideration to the sensitivity of human genetic data and establish an appropriate level of protection for these data and biological samples.

Article 5 of the 2003 International Declaration identifies the purposes of collecting, storing, using, and processing human genetic and proteomic information. The list of purposes is open-ended per se; the use of biological information should not conflict with the Universal Declaration on the Human Genome and Human Rights and the international law of human rights.

The Appendix to Recommendation of the Committee of Ministers of the Council of Europe CM/Rec (2016) 6 is a very significant act for the issue under consideration; it deals directly and in detail with the formation and management of collections of biological materials of human origin (Council of Europe, 2016).

Thus, according to Article 16, the person and/or institution responsible for collecting should be designated and this information should be publicly available. The purposes of the collection should be specified. The principles of transparency and accountability should govern its management, including, where appropriate, access to, use, and transfer of biological materials, and disclosure of information.

Any change of purpose of a collection should be subject to an independent examination of its compliance with the provisions of this recommendation and, where necessary, may require that appropriate consent or authorization of the persons concerned be requested. Each sample of biological material in the collection should be appropriately documented and traceable, including information on the scope of any consent or authorization.

Quality assurance measures should be taken, including conditions to ensure appropriate security and confidentiality during the establishment of the collection, as well as storage, use, and, where appropriate, transfer of biological materials.

Procedures should be established for any transfer of the whole or part of the collection, as well as for the closure of the collection; these should be in accordance with the original consent or authorization.

Information about the management and use of the collection should be made available to the persons concerned and should be regularly updated.

Reports on past and planned activities should be made public at least annually, including information about access granted to biological materials and progress on research projects using biological materials. A summary of the findings should be made public on the completion of each research project.

Any proposal to establish a collection of biological materials should be subject to an independent

examination of its compliance with the provisions of this recommendation. Each collection should be subject to independent oversight which is proportionate to the risks involved for the persons whose biological materials are stored in the collection. Such oversight should aim in particular at safeguarding the rights and interests of the persons concerned in the context of the activities of the collection.

Oversight mechanisms should cover, at a minimum: the implementation of security measures and procedures on access to, and use of, biological materials; the publication, at least annually, of reports on past and planned activities, including information about access granted to biological materials and progress on research using biological materials; the change in the risks to persons whose biological materials are stored in the collection and, where appropriate, revision of policies.

It should be emphasized that, according to Article 19 of the Appendix to Recommendation of the Committee of Ministers of the Council of Europe CM/Rec (2016) 6 (Council of Europe, 2016), biological materials should only be transferred to another State if an appropriate level of protection is either ensured by the law of that State or by legally binding and enforceable instruments adopted and implemented by the parties involved in the transfer for future research activities. And it is noted that the transfer of biological materials should be done under appropriate safety and confidentiality conditions, and also that a documented agreement between the sender of the biological materials and the recipient should be signed. Appropriate consent or authorization, including, where appropriate, any relevant restriction defined by the person concerned, should be included in the agreement.

Approaches to Legal Regulation of Biobanking Issues in Russia

No specific federal law has been adopted in this regard in Russia. According to Article 37 of the Federal Law “On Biomedical Cell Products”, the requirements for the organization and activities of biobanks and the rules for storing biological material are established by the authorized federal executive body (Corpus of Legislative Acts of the Russian Federation, 2016).

In pursuance of this norm, the order of the Ministry of Health of the Russian Federation No. 842n of October 20, 2017, approved the Requirements for the organization and operation of biobanks and the rules for storing biological material, cells for the preparation of cell lines, cell lines intended for the production of biomedical cell products, and biomedical cell products (Ministry of Health of the Russian Federation, 2017).

In this order the biobanks are understood as objects – collections, repositories; properties of the subject are assigned to the developers of biomedical cell products, manufacturers, organizations that arrange and conduct clinical research of biomedical cell products, their sale, use, and storage.

The legal logic of the order is somewhat different from that prescribed by law. The law clearly states the establishment of requirements for the organization and operation of biobanks, and activities presuppose subjectivity. A thing (collection, storage) cannot carry out activities.

By virtue of its logic, and unlike the European approach, this order limits the requirements to purely technical issues. Thus, according to clause 3 of the Requirements, storage conditions for biological objects and biomedical cell products shall enable the preservation of the biological properties of biological objects and biomedical cell products and prevent their infection and contamination, by creating temperature and humidity conditions in the premises (zones) for storing biological objects and biomedical cell products, hygienic regime and light mode.

According to clause 4 of the Requirements, the head of the subject (entity) for circulation of a biomedical cell product shall be obliged to ensure the approval of documents that regulate, among other things, the procedure for performing actions by employees when storing biological objects and biomedical cell products in biobanks; the procedure for servicing and calibrating measuring instruments and equipment in biobanks; maintaining records, reports and storage thereof; reception, transportation, and placement of biological objects and biomedical cell products in biobanks.

Under clause 5 of the Requirements, the quality system should ensure that:

1) the transportation of biological objects and biomedical cell products within the biobank ensures their storage;

2) the entity employees’ responsibility for violation of the requirements and standard operating procedures is determined;

3) documentary registration of measures for the storage of biological objects and biomedical cell products in biobanks and the results achieved is carried out during the implementation or immediately after the completion of the relevant measures;

4) for each violation of the requirements, an internal audit is carried out and corrective measures are developed to eliminate the identified violations.

Obviously, the document overlooked the issues of confidentiality, voluntary informed revocable consent, and others related to legal, rather than to purely technical aspects (Sarmanaev, Shirokov, Vasiliev, Osavelyuk, Zenin, and Suvorov, 2019).

At the same time, the law itself contains the most important requirements for the functioning of biobanks. Thus, according to Article 3 of the law, the principles for the implementation of activities in the field of circulation of biomedical cell products include voluntariness and gratuitousness of biological material donation; observance of medical confidentiality and other legally protected privacy; inadmissibility of buying and selling biological material; the inadmissibility of creating a human embryo for the production of biomedical cell products; the inadmissibility of the use of biomedical cell products of biological material derived by interrupting the development of a human embryo or fetus or by disrupting such a process for the development, production, and use; compliance with biological safety requirements to protect the health of donors of biological material, workers involved in the production of biomedical cell products, medical workers, patients, and the environment.

Approaches to the Legal Regulation of the Commercial Use of the Genomic Research Results

The legal regulation of the possibilities for commercial use of the genomic research results is still at the stage of formation nowadays, and many questions arise in this process, both of a formal legal and ethical nature (Kalinichenko and Ponomareva, 2019).

Fundamentals of International Legal Regulation of the Possibilities for the Commercial Use of Human Genome Research Results

Thus, in the system of international legal regulation, the situation is as follows.

At the universal level, within the framework of the UN, WHO, or UNESCO, no international treaties in the field of our interest have been adopted.

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (the Oviedo Convention) (Council of Europe, 1997) is the only international treaty that partially regulates this issue. The Russian Federation, like several other states, for example, Belgium, the United Kingdom, Germany, Ireland, do not participate in the convention; Italy, Luxembourg, the Netherlands, Poland, and Sweden have not yet ratified the convention (Council of Europe, 2020).

It should be noted that such a situation makes the significance of this treaty very modest, which is probably related to some contradictions and limitations of the norms contained therein.

For the purposes of the topic under study, the convention must establish several direct prohibitions (Kubyshkin, Kosilkin, and Astrelina, 2019).

Thus, according to Article 21 of the Oviedo Convention, the human body and its parts should not, as such, be a source for financial gain. Therefore, trading in donor organs and tissues is expressly prohibited, but this prohibition does not seem to refer to commercial use of the results of genomic research.

The second criterion, which appears in Article 21, is that the human body and its parts should not give rise to financial gain “as such”. And thereby, not the body, but manipulations with the body, organs, and tissues can already serve as a source of legitimate income.

Another important principle is stated in Article 13 of the Convention, according to which 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.

Herewith, somatic gene therapy, which is not associated with modifications in the genome of the descendants, is already being used (Watson, Berry, and Davies, 2019). The safety of germline editing methods has not yet been proven, although relevant studies are conducted, for example, in the UK (Fogarty, McCarthy, Snijders, Powell, Kubikova, Blakeley, Lea, Elder, Wamaitha, Kim, Maciulyte, Kleinjung, Kim, Wells, Vallier, Bertero, Turner, and Niakan, 2017) and Russia (Kodyleva, Kirillova, Tyshchik, Makarov, Khromov, Guschin, Abubakirov, Rebrikov, and Sukhikh, 2018).

Thus, Article 13 allows, in principle, intervention into the human genome aimed at modifying it, but explicitly prohibits intervention aimed at modifying the genome of the descendants of a given person.

The cited norm of Article 13 is criticized by researchers. They voice fears that the established absolute prohibition could potentially deprive a patient suffering from hereditary, genetically determined diseases of the possibility of experimental treatment so far, thereby violating even more fundamental rights and principles, in particular the right to life (Montgomery, 2018). Additionally, it should be underlined that back in 2018, experts from the Nuffield Council on Bioethics in the UK stated that "while the law should not currently be changed to allow human genome editing to correct genetic faults in offspring, future legislation permitting it should not be ruled out" (Kelland, 2018).

Similar standards are laid down in international advisory acts. Thus, Article 4 of the UNESCO Universal Declaration on the Human Genome and Human Rights of 1997 enshrines the principle that "the human genome in its natural state shall not give rise to financial gain" (United Nations Educational, Scientific and Cultural Organization, 1997). In our opinion, this principle sounds somewhat declarative. Indeed, the genome as a whole cannot be in civilian circulation. However, based on the literal interpretation of this article, it is not prohibited to derive profit from genome modification.

Consequently, it can be argued that international law today does not contain a ban on the commercial use of genomic research results.

Review of Some Lawsuits Concerning the Commercial Use of the Genomic Research Results

Commercial interests exert a similar impact on how people perceive the acceptability of different forms of consent. A 2016 study showed that the majority of people (68%) were willing to give their blanket consent that their tissues, organs, etc. can be used for any research study approved by the biobank, but their number dropped to 55% if their specimens might be used "to develop patents and earn profits for commercial companies (De Vries and Tomlinson, 2016).

1. Greenberg v. Miami Children's Hospital Research Institute (USA) 2003

The plaintiffs in the case were parents of children afflicted with Canavan disease who provided tissue for the research, as well as three non-profit organizations that developed a confidential Canavan database and registry (Moreno, 2003). The plaintiff families also helped identify other children internationally to involve in the research, which is significant since this disorder is an orphan disease and the number of participants directly affects the research results. The defendants were medical researcher Dr. Reuben Matalon (who isolated and patented the ASPA gene sequence and developed genetic screening tests for it) and the Miami Children's Hospital where he conducted his research. The US District Court for the Southern District of Florida dismissed several of the plaintiffs' motions, including lack of informed consent, breach of fiduciary duty, fraudulent concealment of the patent, and misappropriation of trade secrets. However, the court adjudged the tissue donors' unjust enrichment claim on the grounds that the participants had in fact invested time and significant resources in searching for disease mechanisms.

The defendants argued that the law did not contain the obligation of the researcher to disclose the conflict of interest and the possible benefits of the research in informed consent, which participants were asked to sign. According to the defendants, disclosing economic interests to the research participants may give donors the right to control how medical research is carried out and who benefits therefrom, and this situation creates the risk of abuse of this right. The court agreed with this argument.

2. Estate of Gelsinger v. Trustees of University of Pennsylvania (USA)

This case reflects a conflict of interest in a gene therapy trial, and also demonstrates the impact of having an economic dimension in research design. Jesse Gelsinger died in the course of a clinical trial; the doctors in charge were found guilty, and their actions were qualified as negligence. The dispute was resolved by paying several million dollars to the affected family. However, the dispute is also interesting in that it had a conflict of interest: the director of the institute leading the research and the University of Pennsylvania itself had significant financial interests in a biotech company that was going to bring the therapy to the market after all stages (preclinical, clinical trials, registration). In fact, the dean of the medical school and the lead investigator of the study stood to benefit financially from the commercialization of the therapy through their patent ownership. In addition, the academic medical center also had an equity stake in the biotechnology

company collaborator and would have profited from commercialization.

This case influenced an amendment in the existing legislation in terms of the obligation to disclose the conflict of interest and the desire of responsible researchers to commercialize research (Liang and Mackey, 2010; Wilson, 2010).

3. Case of Henrietta Lacks + Moore v. Regents of University of California, 793 P.2d 479 (Cal. 1990) (USA)

In 1951, Henrietta Lacks was diagnosed with cancer. A biopsy sample of her cancer cells was sent to a nearby laboratory without her consent and given to other doctors in an attempt to grow human cells outside the body. Today, HeLa cells – after the first two letters of her first and last name – are being used to study the effects of toxins, drugs, hormones, and viruses on cancer cell growth without human experimentation. They were used to test the effects of radiation and poisons, to study the human genome, to learn more about how viruses work and were pivotal in the development of a polio vaccine. The biomaterial has been used for both medical research and commercial purposes.

There are 17,000 HeLa cell patents in the US that continue to make money. In 2017, Johns Hopkins University released a statement denying it had profited from the cells (Brown, 2018). However, the Lacks family did not receive any financial profits gained from the research of the HeLa cells, as did Henrietta herself, who died of her disease in 1951, at 31.

There was a similar story in the Moore case (Panelli, 1990), but in this instant, this case came to trial. The plaintiff John Moore had cancer and underwent treatment at the Medical Center of the University of California at Los Angeles (UCLA Medical Center), where his doctor was withdrawing extensive amounts of blood and other biosamples from the plaintiff for several years. As a result, a "Mo cell line" was established, patented, and used commercially. The patent was issued on March 20, 1984, and it lists the defendants Dr. David W. Golde (Moore's physician) and Shirley G. Quan (a researcher) as inventors. The defendants, Genetics Institute Inc. and Sandoz Pharmaceuticals Corporation, were involved in a dispute over their investment in research with a controversial cell line.

4. Association for Molecular Pathology v. Myriad Genetics, Inc. (133 S. Ct. 2107) 2013 and Mayo Collaborative Services v. Prometheus Laboratories, Inc. (132 S. Ct. 1289) 2012

Myriad Genetics Inc. had licensed several patents from the University of Utah, the National Institutes of Health, and several other government and academic institutions that describe the exact location and sequencing of the *BRCA1* and *BRCA2* genes. These patents also described certain mutations in *BRCA1* and *BRCA2* genes that significantly increased the risk of developing breast and ovarian cancer. In licensing these patents, Myriad then developed diagnostic tests to detect whether a patient's sample had the mutations in *BRCA1* or *BRCA2*. In an effort to protect its business model, Myriad sued a clinical lab that was competing with Myriad's breast cancer tests (Wales and Cartier, 2015).

Nearly a decade after that claim was rejected and after Myriad brought *BRCA* testing into the mainstream, patients, advocacy groups, doctors, and the Association for Molecular Pathology filed suit. The district court held that the challenged claims were invalid because they covered products of nature. On appeal, this decision was partially reversed, with the federal court finding that both isolated DNA and complementary DNA (cDNA) were the patentable subject matter.

This decision was then appealed to the U.S. Supreme Court, which held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that the cDNA is patent-eligible because it is not naturally occurring". In fact, the Supreme Court believed that "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention" and that "groundbreaking, innovative or even brilliant discovery does not by itself satisfy" patent eligibility.

In reaching its decision, the Supreme Court did acknowledge that synthetic DNA (e.g., cDNA) was patentable.

Prometheus Laboratories, Inc. is the sole and exclusive licensee of patents at issue and sells diagnostic tests based on these patents which concern the proper use of thiopurine drugs to treat autoimmune diseases. When ingested, the body metabolizes the drugs differently, doctors have found it difficult to

determine the dosage and evaluate risks in each specific case. Mayo Collaborative Services and Mayo Clinic Rochester (Mayo) bought and used diagnostic tests based on Prometheus' patents. But in 2004 Mayo announced that it intended to sell and market its own, somewhat different, diagnostic test. Prometheus sued Mayo in June 2004 contending that Mayo's test infringed its patents. In March 2008 the District Court held the patents invalid. The Court acknowledged the correlations between thiopurine metabolite levels and the toxicity and efficiency of thiopurine drugs not patentable by the laws of nature and affirmed that there was no inventive concept in the claimed application of the natural laws. This decision is considered one of the most controversial decisions in patent litigation in the biotechnology field (LexisNexis, 2012).

5. Washington University v. Catalona 2007

In the early 1980s, Dr. William J. Catalona at the University of Washington began asking his patients if they were willing to let him use the tissue he removed during surgery for research. After obtaining their consents, he collected tens of thousands of tissue samples.

His research led to the development of the PSA (Prostate Specific Antigen) test, which is used to detect prostate cancer (Washington University v. Catalona, 2006). In 2001, Dr. Catalona requested the University confirmation to send a limited number of samples to a biotech company to evaluate the effectiveness of a new test to identify prostate cancer. He intended to use the research results for academic purposes and publications. He understood that the research results would be beneficial for treating men at risk of developing the disease. The University did not give permission, planning to independently commercialize the research results – to sell a collection of biosamples.

Because of controversy with the University of Washington, Dr. Catalona decided to move his practice to Northwestern University's medical school in Chicago. Washington University filed a lawsuit against Dr. Catalona, asking the court to declare it to be the owner of the research participants' samples, which it claimed were worth over one million dollars.

The trial court decreed that Washington University is the owner of the tissue and the research results. The Court held that under the specific facts of the case, the men who participated had given their tissue to the University as a gift and they could not get it back. However, the Court decision confirmed that the men retained the right to stop participating in the research 1) by declining to answer any additional questions; 2) by not donating more tissue, or 3) by disallowing the use of their tissue in future research.

6. CHEO v. US-based Transgenomic, Inc. (Long QT Gene Patents) (Canada) 2014

Currently, the legal "legacy" of gene patenting does not allow physicians to take full advantage of genetic technology (Long QT test).

Children's Hospital of Eastern Ontario (CHEO) in Ottawa conducts genetic tests to detect the risk of long QT syndrome (hereditary heart rhythm disorder). Because previously Transgenomic Inc., the US company, patented some genes and tests, the CHEO researchers could not screen the patients full-fledged (Rice, 2016).

CHEO attempted to challenge the patent on genes owned by Transgenomic Inc., once again raising the question of the legality of gene patents.

The dispute resulted in an agreement on public access to health in Canada: Transgenomic provided CHEO and other Canadian hospitals and public sector laboratories the right to conduct genetic testing on a not-for-profit basis. The agreement, in particular, upholds the patent, stating that the company reserves all rights to use, commercialize, license, and otherwise exploit all aspects of the long QT patents for any use or purpose (Melnitzer, 2016).

CONCLUSION

The authors are seriously concerned about the implementation of the principle of priority of human life and health over the interests of science and society, enshrined in some international regional legal acts. This opposition not only does not contribute to the development of science and society, but ultimately hinders the provision of life and health of humanity in general and of individuals in particular, that is, it leads to a negative effect in any case, no matter what interests are put at the forefront. In our opinion, it makes no sense to determine which interests are more priority - a particular person or science in general. It is necessary to define and find a balance between these interests. Only a balanced approach will help avoid many negative situations.

With regard to the legal regulation of genome research, there are different approaches to the genome

and all information related to its decoding and subsequent processing both at the international level and in national law. Unification of approaches would be highly desirable, at least it would make sense to expand international cooperation in this direction.

In particular, certain questions are raised by the possibility, principles and limits of the commercial use of the results of genomic research.

According to the authors, international law today does not contain a prohibition on such use, while a system of criteria, principles and norms is being formed.

A review of some court cases in the field of commercial use of the results of genomic research shows an increasing interest in society and in the field of economic activity in the field of genomic research, and also indicates that judicial systems, even in the absence of clear legal regulation, relying on general legal approaches and principles, develop their own approaches to resolving relevant disputes.

The issues of the legal status of biobanks are closely related to genome research. Unfortunately, there are currently no international treaties directly dedicated to biobanking issues. Obviously, this is a matter for the near future. There is still no unified legal definition of a biobank. On the one hand, a biobank means a collection of biological materials taken from several donors, on the other hand, a specialized organization acting under a permit (license) and under the direct control of state bodies, for scientific and medical purposes. In the Russian Federation, at the level of the law, it is prescribed that the legal regulation of the activities of biobanks at the sub-legal level should be carried out based on the understanding of the biobank as a subject. Nevertheless, at the moment, legal regulation at the level of by-laws is carried out on the basis of understanding the biobank as an object, which does not allow us to speak about the proper state of legal regulation in this area, since many sensitive issues are not covered by legal regulation, which leads to a state of considerable uncertainty.

In addition, we believe that a transparent exchange of views on the issues under consideration between specialists from different countries, different legal systems is very important for the progressive development of science in general and legal research in particular.

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REFERENCES

Brown, D. L. (2018). *Can the 'Immortal Cells' of Henrietta Lacks Sue for Their Own Rights?* https://www.washingtonpost.com/news/retropolis/wp/2018/06/25/can-the-immortal-cells-of-henrietta-lacks-sue-for-their-own-rights/

Chen, H., Chan, B., & Joly, Y. (2015). Privacy and biobanking in China: A case of policy in transition. *The Journal of Law Medicine & Ethics*, 43(4), 726-742. https://doi.org/10.1111/jlme.12315

Council of Europe. (1997). *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.* https://rm.coe.int/168007cf98

Council of Europe. (1998). *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings.* https://rm.coe.int/168007f2ca

Council of Europe. (2016). *Recommendation CM/Rec(2016)6 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin.* https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=090000168064e8ff

Council of Europe. (2020). Chart of Signatures and Ratifications of Treaty 164. https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p_auth=F4uxBQvK

De Vries, R. G., & Tomlinson, T. (2016). *Americans Want a Say in What Happens to Their Donated Blood and Tissue in Biobanks.* https://theconversation.com/americans-want-a-say-in-what-happens-to-their-donated-blood-and-tissue-in-biobanks-60681

European Court of Human Rights. (2015). ECHR 2015/20 Case of Parillo v. Italy, 27 August 2015, no. 46470/11 (Grand Chamber).

European Court Reports. (2011). *Case C-34/10, Oliver Brüstle v Greenpeace eV.* http://curia.europa.eu/juris/liste.jsf?language=en&num=C-34/10

European Free Trade Association. (2020). *Protocol 31 to the EEA Agreement on Cooperation in Specific Fields outside the Four Freedoms.* https://www.efta.int/media/documents/legal-texts/eea/the-eea-agreement/Protocols%20to%20the%20Agreement/protocol31.pdf

Fogarty, N. M. E., McCarthy, A., Snijders, K. E., Powell, B. E., Kubikova, N., Blakeley, P., Lea, R., Elder, K., Wamaitha, S. E., Kim, D., Maciulyte, V., Kleinjung, J., Kim, J. S., Wells, D., Vallier, L., Bertero, A., Turner, J. M. A., & Niakan, K. K. (2017). Genome editing reveals a role for OCT4 in human embryogenesis. *Nature*, 550(7674), 67–73. https://doi.org/10.1038/nature24033

Goldberg, R., & Lonbay, J. (2000). *Pharmaceutical Medicine, Biotechnologies and European Law*. Cambridge: Cambridge University Press. https://doi.org/10.1017/CBO9780511560125

Kalinichenko, P. A., & Nekoteneva, M. V. (2020). Specifics of legal regulation in genomic researches at the international and european level. *Courier of Kutafin Moscow State Law University (MSAL))*, 4, 68-78. https://doi.org/10.17803/2311-5998.2020.68.4.068-078

Kalinichenko, P. A., & Ponomareva, D. V. (2019). Ethical and legal aspects of regulating genomic research in international and Russian practice. *Medical Radiology and Radiation Safety*, 64(5), 69–70. https://doi.org/10.12737/1024-6177-2019-64-5-69-70

Kelland, K. (2018). UK Ethics Body Says Gene-Edited Babies May Be 'Morally Permissible'. https://www.reuters.com/article/us-health-genome-ethics-idUSKBN1K62VI/

Kodyleva, T. A., Kirillova, A. O., Tyshchik, E. A., Makarov, V. V., Khromov, A. V., Guschin, V. A., Abubakirov, A. N., Rebrikov, D. V., & Sukhikh, G. T. (2018). The efficacy of CRISPR-CAS9-mediated induction of the CCR5DELTA32 mutation in the human embryo. *Bulletin of the Russian State Medical University,* 4, 80-83. https://doi.org/10.24075/vrgmu.2018.052

Kubyshkin, A. V., Kosilkin, S. V., & Astrelina, T. A. (2019). International legal regulation of genetic research, bio-banking, bioinformatics and human reproduction: analysis of the main international legal acts. *International Legal Courier*, 2(19), 29-34. http://inter-legal.ru/wp-content/uploads/2019/10/21-10-web.pdf

Lander, E., Baylis, F., Zhang, F., Charpentier, E., Berg, P., Bourgain, C., Friedrich, B., Joung, J. K., Li, J., Liu, D., Naldini, L., Nie, J.-B., Qiu, R., Schoene-Seifert, B., Shao, F., Terry, S., Wei, W., & Winnacker, E.-L. (2019). Adopt a moratorium on heritable genome editing. *Nature*, 567, 165-168. https://doi.org/10.1038/d41586-019-00726-5

LexisNexis. (2012). *Mayo Collaborative Servs. v. Prometheus Labs., Inc. - 566 U.S. 66, 132 S. Ct. 1289*. https://www.lexisnexis.com/community/casebrief/p/casebrief-mayo-collaborative-servs-v-prometheus-labs-inc-834664167

Liang, B. A., & Mackey, T. (2010). *Addressing Institutional Conflict of Interest to Promote Patient Safety.* https://www.psqh.com/analysis/addressing-institutional-conflict-of-interest-to-promote-patient-safety/

Melnitzer, J. (2016). *Canadian Patent Settlement Sets Model for Not-For-Profit Gene Testing.* https://business.financialpost.com/legal-post/canadian-patent-settlement-sets-model-for-not-for-profit-gene-testing

Ministry of Health. (2006). Directives for Private Healthcare Institutions Providing Assisted Reproduction Services (4.11.2(ii)), 1-10.

Ministry of Health and Social Affairs, Sweden. (2002). *Biobanks in Medical Care Act.* https://biobanksverige.se/wp-content/uploads/Biobanks-in-medical-care-act-2002-297.pdf

Ministry of Health of the Russian Federation. (2017). *Order No. 842n "On Approval of the Requirements for the Organization and Operation of Biobanks and Rules for Storing Biological Material, Cells for the Preparation of Cell Lines, Cell Lines Intended for the Production of Biomedical Cell Products".* http://pravo.gov.ru/

Ministry of Social Affairs and Health, Finland. (2012). *Biobank Act.* https://finlex.fi/fi/laki/kaannokset/2012/en20120688.pdf

Ministry of Welfare. (2014). *The Biobanks and Health Databanks Act.* https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Biobanks-Act-as-amended-2015.pdf

Montgomery, J. (2018). Modification of the human genome: human rights challenges raised by scientific and technical developments. *Precedents of the European Court of Human Rights*, 3(51), 42-56.

Moreno, F. A. (2003). *Greenberg v. Miami Children's Hospital RES. INST., INC., 264 F. Supp. 2d 1064 (S.D. Fla. 2003).* https://www.courtlistener.com/opinion/2507167/greenberg-v-miami-childrens-hospital-res-inst-inc/

Murtazin, M. F. (2003). *Resolutions and Recommendations of the Council of the Islamic Fiqh Academy.* Moscow: Ladomir.

Panelli, E. A. (1990). *Moore v. Regents of University of California, 793 P.2d 479 (Cal. 1990).* https://www.courtlistener.com/opinion/2608931/moore-v-regents-of-university-of-california/?

Presidência da República. (2005). *Brazilian Biosafety Law No. 11.105.* http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Lei/L11105.htm#art42

President of Russia. (2016). *Law No. 180-FZ "On Biomedical Cell Products".* http://www.kremlin.ru/acts/bank/40894

Pribitkov, K. (2019). *WHO Has Formed an Expert Committee to Assess the Consequences of Changes in Human Genes.* https://tass.ru/obschestvo/6119748

Rial-Sebbag, E., & Pigeon, A. (2015). Regulation of biobanks in France. *Journal of Law, Medicine and Ethics*, 43(4), 754-765. https://doi.org/10.1111/jlme.12317

Rice, W. (2016). *CHEO Reaches 'Historic' Settlement with Gene Patent Owner.* https://www.cbc.ca/news/canada/ottawa/cheo-gene-patent-lawsuit-settlement-1.3483433

Riigi Teataja. (2001). *Human Genes Research Act.* https://www.riigiteataja.ee/en/eli/531102013003/

Sarmanaev, S. Kh. Shirokov, A. Yu., Vasiliev, S. A., Osavelyuk, M. A., Zenin, S. S., & Suvorov, G. N. (2019). Proposals for extending the Russian biobanks functions to protect genomic information. *Lex Russica,* 6(151), 153-160. https://doi.org/10.17803/1729-5920.2019.151.6.153-160

The European Parliament. (2008). *Joint Parliamentary Committee 30th Meeting of the EEA Joint Parliamentary Committee. Resolutions and Recommendations.* https://www.europarl.europa.eu/cmsdata/146634/20080626ATT32804EN.pdf

The European Parliament and the Council of the European Union. (1998). *Directive No. 98/44/EC of the European Parliament and the Council of the European Union "On the Legal Protection of Biotechnological Inventions.* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044

The European Parliament and the Council of the European Union. (2004). *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells.* https://op.europa.eu/de/publication-detail/-/publication/1589d23a-1fd2-40aa-83cb-b8641cb53165/language-en

The Japan Society of Human Genetics, Council Committee of Ethics, Matsuda, I., Niikawa, N., Sato, K., Suzumori, K., Fukushima, Y., Fujiki, N., Kanazawa, I., Nakamura, Y., Yonemoto, S., & Nakagome, Y. (2001). Guidelines for genetic testing. *Journal of Human Genetics*, 46(3), 163-165. https://doi.org/10.1007/s100380170107

Tkachuk, V. V. (2019). Consequences of the EU Court Judgment in the "Oliver Brüstle V Greenpeace Ev" Case for genomic researches within the European Union. *Courier of Kutafin Moscow State Law University (MSAL)*, 4, 138-145. https://doi.org/10.17803/2311-5998-2019-56-4-138-145

United Nations. (2005). *United Nations Declaration on Human Cloning.* https://doi.org/10.1515/jibl.2005.2.5.211

United Nations Educational, Scientific and Cultural Organization. (1997). *Universal Declaration on the Human Genome and Human Rights.* http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html

United Nations Educational, Scientific and Cultural Organization. (2003). *International Declaration on Human Genetic Data.*

http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

Wales, M., & Cartier, E. (2015). The Impact of Myriad on the Future Development and Commercialization of DNA-Based Therapies and Diagnostics. *Cold Spring Harbor Perspectives in Medicine,* 5(12), a020925. https://doi.org/10.1101/cshperspect.a020925

Washington University v. Catalona. (2006). https://caselaw.findlaw.com/us-8th-circuit/1300306.html

Watson, J. D., Berry, A., & Davies, K. (2019). *DNA: The Story of the Genetic Revolution.* St. Petersburg: Peter.

Wet op bijzondere medische verrichtingen. (1997). https://wetten.overheid.nl/BWBR0008974/2012-01-01

Wilson, R. (2010). The death of Jesse Gelsinger: New evidence of the influence of money and prestige in human research. *American Journal of Law & Medicine*, 36(2-3), 295-325. https://doi.org/10.1177/009885881003600202

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