https://doi.org/10.17803/lexgen-2023-2-1-61-78

Original article / Оригинальная статья

Legal Regulation of Patenting the Results of Genomic Research at the Global, Regional and National Level

Maria V. Nekoteneva✉, **Daria V. Ponomareva**
Kutafin Moscow State Law University (MSAL), Moscow, Russian Federatio

Abstract

This article analyzes the legal regulations concerning the patenting of the results of genomic research at the international, regional and national levels. The authors identify specific areas of copyright protection of the results of genomic research at universal and regional levels (for example, within the framework of integration organizations), as well as topical legal problems which recur in national legislation. The authors pay special attention to the analysis of judicial practice which illustrates patients' rights (access to the information, the ability to use the results of genomic research, etc.) and the rights of participants carrying out genomic research. The article may be of interest to legal scientists, practitioners and specialists in human genome research (biomedicine, bioinformatics, medicine, human reproduction, etc.).

Keywords: international law, protection of the rights of patients, copyright protection, patenting, genomic research, DNA, European law, international standards

To cite this article: Nekoteneva, M. V., & Ponomareva, D. V. (2023). Legal regulation of patenting the results of genomic research at the global, regional and national level. *Lex Genetica*, 2(1), 61–78. https://doi.org/10.17803/lexgen-2023-2-1-61-78

Received 20.05.2023
Revised 15.06.2023
Accepted 20.07.2023

Правовое регулирование патентования результатов геномных исследований на глобальном, региональном и национальном уровнях

✉Email: mvnekoteneva@msal.ru

Мария В. Некотенева✉, **Дарья В. Пономарева**
Университет имени О.Е. Кутафина (МГЮА), Москва, Российская Федерация

Аннотация

В данной статье анализируется правовое регулирование патентования результатов геномных исследований на международном, региональном и национальном уровнях. Авторы выделяют конкретные направления охраны авторских прав результатов геномных исследований на международном и региональном уровнях (например, в рамках интеграционных организаций), а также актуальные правовые проблемы, которые встречаются в национальном законодательстве. Особое внимание уделяется анализу судебной практики, иллюстрирующей права пациентов (доступ к информации, возможность использования результатов геномных исследований и др.) и права участников, которые проводят геномные исследования. Статья может быть интересна ученым-юристам, практикам и специалистам в области исследования генома человека, биомедицины, биоинформатики, медицины, репродукции человека и др.

Ключевые слова: международное право, защита прав пациентов, защита авторских прав, патентование, геномные исследования, ДНК, европейское право, международные стандарты

Для цитирования: Некотенева М.В., Пономарева Д.В. (2023). Правовое регулирование патентования результатов геномных исследований на глобальном, региональном и национальном уровнях. *Lex Genetica*, 2(1), 61–78. https://doi.org/10.17803/lexgen-2023-2-1-61-78

Поступила 20.05.2023
Пересмотрена 15.06.2023
Принята 20.07.2023

Introduction

The rapid development of science and technology has opened up new opportunities for advancing innovative methods of treating diseases and improving the quality of life of terminally ill patients. At the present time genetic testing, screening, genetic data collection and gene therapy contribute to timely diagnosis and successful treatment, prevent the progress of disease, and can reduce the risk of having an unhealthy child etc.

Modern technologies allow for various genetically related anomalies to be tested not only before the onset of a pronounced disease, but also in the absence of any disease markers (for many years before their manifestation) and even before conception. The broad options of using the results of such research are not limited to medicine; they are also of interest to researchers in the sphere of agriculture, industrial safety, banking services, etc.

✉Email: mvnekoteneva@msal.ru

The technological leaps in the field of genetics, as well as the surge of public interest in this sphere have fostered the growth of the state`s role in financing the genomic research, as well as the number of private investors interested in research and development projects in the field of biotechnology and pharmaceuticals.

The research methodology includes: dialectical, logical, predictive methods, systems and content analysis, statistical, comparative and technical legal methods.

Legal framework at the international level. General review

The issue being considered here is linked to the correlation between the protection of the commercial interests of scientists involved in genomic research and the protection of the rights of patients.

Patents provide a way of protecting the commercial interests of genomic research participants. The ability of modern patent law to adapt to new genomic technologies and ensure proper legal regulation remains controversial.

A patent is a document issued by a specialized body that restricts other interested parties in the production, use, sale, import of the invention claimed in the patent. This right is enforced by national courts. A patent provides the right to legal protection to its owner against any person desirous of reproducing, using or selling the invention without permission.

On the one hand, patenting and trade, including international trade, facilitate the transfer of technology and the commercialization of genomic research. On the other hand, it can lead to a number of violations of fundamental human rights.

The aim of the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine[1] is 'to protect human dignity and fundamental human rights and freedoms with regard to the applications of biology and medicine'. The participating States agree to 'protect the dignity and the identity of all human beings', and the Additional Protocol of No-Cloning[2] states that 'the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes an abuse of biology and medicine'.

It is assumed that the dignity of the first clones cannot be adequately protected, since they would be subjected to undue public scrutiny, contempt or other negative treatment.

The right to protect the genetic information of an individual as a part of personal data includes: compliance with measures to protect against disclosure of relevant information by per-sons who have access to genomic information; admissibility of collection, pro-

[1] The 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 ETS N 164 (adopted by the Committee of Ministers of the Council of Europe on November 19, 1996). Available at: http://www.spbraaci.ru/files/164_CE_Convention_eng.pdf

[2] Additional Protocol to the Convention for the Protection of Human Rights and Human Dignity in Relation to the Application of Biology and Medicine, Concerning the Prohibition of the Cloning of Human Beings ETS N 168 (Paris, 12 January 1998). Available at: https://www.insdip.com/wp-content/uploads/2020/12/Additional-Protocol-on-the-Prohibition-of-Cloning-Human-Beings-Convention-for-the-Protection-of-Human-Rights-de-1998.pdf

cessing, storage of the specified information (Kubyshkin, 2021).

Non-discrimination and equal protection are enshrined both in acts developed within the framework of the UN, the European Union and the Council of Europe. Discrimination may occur when carrying out genetic testing or screening, the results of which may dissuade employers from hiring an applicant for a job, lead to the dismissal of a previously hired employee, or cause insurance companies to refuse an insurance contract (or offer less favorable conditions) because of the test results.

There are also cases of positive discrimination. This may happen when a child subject to genetic manipulations receives advantages as a result of the intervention. He or she may become endowed with new qualities or may develop certain abilities (e.g. he or she may become more intelligent or receive certain creative abilities, etc.). The ban on discrimination puts him or her in a more advantageous position compared to a person who has not been subjected to such manipulations.

At the international level, there are a number of different approaches to the perception of the human genome. The United Nations Educational, Scientific and Cultural Organization describes the human genome as the 'common heritage of mankind'. The principle of this approach is to preserve the human genome as a separate species which means the inadmissibility of changing the genome. Maintaining the balance between the interests of society and the individual and freedom of scientific research entails a number of exceptions, the central idea of which is a prohibition of any modification in the genome of any descendants.

Similarly, the scientific community have varying attitudes towards the possibility of patenting both the genes, processes and results of genomic research.

The main international acts governing the rules for granting patents are:

— *1970 Patent Cooperation Treaty*[3]. This Treaty establishes the International Patent Cooperation Union and defines the global practice according to which a patent application filed in one jurisdiction can be processed in others. Rules 5 and 13 of the Instructions to the Patent Cooperation Treaty contain the following provision: if the international application includes disclosure of nucleotide and/or amino acid sequences, the description must insert a list of these sequences. Rule 9 establishes the limitations under which the international application should not contain provisions contrary to morality and public order (Erstling & Boutillon, 2005).

— *The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*[4]. This Agreement stipulates that 'patents should be available for any invention, whether products or processes, in all areas of technology, provided that they are new, correspond to a certain inventive step, have the possibility of industrial application'. The document establishes

[3] Договор о патентной кооперации (Вашингтон, 19 июня 1970 г.) (пересмотренный 28 сентября 1979 г., измененный 3 февраля 1984 г. и 3 октября 2001 г.). Режим доступа: https://base.garant.ru/2540241/ (дата доступа 10.03.2023).

[4] Соглашение по торговым аспектам прав интеллектуальной собственности (ТРИПС) (ВТО, Уругвайский раунд многосторонних торговых переговоров, 15 апреля 1994 г.) (с изменениями и дополнениями). Режим доступа: https://base.garant.ru/4059989/ (дата доступа 10.03.2023).

the possibility of patenting both the product and the method of its manufacture. The effect of a patent for a method of manufacturing a product extends to the product itself. Within the framework of the Agreement, special attention is paid to biotechnological inventions, since at the time of its adoption, attempts had been made to patent genetically modified foods, drugs and other medical supplies (Defossez, 2017).

There are a number of agreements at the regional level. However, not all of them establish a system which provides for effective protection of intellectual property rights.

In 1976, the African Regional Intellectual Property Organization was established (until 2005 – African Regional Industrial Property Organization). A distinctive characteristic of way in which this matter was regulated within the framework of this organization is the consistent expansion of the range of protected objects. Initially, protection was granted only for inventions and industrial designs, and then a utility model was added. Later, the legal protection of trademarks and service marks was introduced. It should also be noted that the system of the African Regional Intellectual Property Organization does not provide for the issuance of a title of protection valid on the territory of all participating States.

In 1993, the Agreement on Measures to Protect Industrial property within the Framework of the CIS was signed. In addition, the Interstate Council on the Protection of Industrial Property was established. The Eurasian Patent Convention was introduced in 1994 which set up the Eurasian Patent Organization and simplified the issuing of a patent. Individuals and legal entities acquired the opportunity to protect the rights to inventions on the basis of a single Eurasian patent, valid on the territory of all states – party to the Convention. The Eurasian Patent Organization was set up to perform administrative tasks related to the operation of the Eurasian patent system and the granting of Eurasian patents. Russian is the official language of the organization.

EU Law

The legal problem of patenting is considered within the framework of the European Union. The European Patent Office was established by the European Patent Convention of 1973[5]. Certain states outside the European Union also participate in the Convention (e.g., Switzerland, Turkey, Norway). The European Patent Office may issue a patent valid in the signatory states, but these patents must also be officially recognized by the Member States at the national level and are subject to protection within the national jurisdiction. Article 53 of the European Patent Convention contains provisions according to which methods of therapeutic and surgical treatment of a human or animal and methods of medical or veterinary diagnostics are not considered industrially applicable inventions.

Due to a number of difficulties in obtaining patents in accordance with the European Patent Convention (in particular, a complex and expensive translation procedure, the implementation of judicial protection in national courts, etc.) (Ellyne, 2014), the Commission of the European Union proposed the introduction of a unitary European patent in 2000.

[5] Конвенция о выдаче европейских патентов. Режим доступа: https://rospatent.gov.ru/content/uploadfiles/exhibition_corr_ormatted.pdf (дата доступа 10.03.2023).

After lengthy discussions, the following documents were adopted: Regulation of the European Parliament and of the Council of the EU No. 1257/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection[6] and Council Regulation No. 1260/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements[7]. The signing of the Agreement on the establishment of a Unified Patent Court on February 19, 2013[8] was one of the final steps towards the creation of a uniform mechanism for obtaining and protecting patents within the EU.

Of special interest is the European patent application 0 169 672 published on January 29, 1986. This relates to a method for obtaining a transgenic animal (rodent), the germ and somatic cells of which contain an activated oncogene sequence. The method for obtaining a transgenic animal involves introducing an activated oncogene sequence into the animal's genome[9].

Initially, the Examination Division rejected this application since the invention did not meet the requirements of the European Patent Convention. Pursuant to Article 53, European patents are not granted for varieties of plants or animal breeds, or predominantly biological methods for breeding plants or animals and inventions, the commercial exploitation of which would be contrary to public order or morality.

Nevertheless, the Appellate Chamber issued a judgment to grant a patent. This judgment plays a key role in the history of European patent law relating to the patenting of transgenic animals, allowing for the patenting of such objects. When analyzing the application, the Appellate Chamber came to certain conclusions, especially those relating to the moral and ethical issues of patenting biotechnological inventions, which were used later when considering other disputable situations in the EPO Appellate Chambers. They were also included in Directive 98/44 / EC on the legal protection of biotechnological inventions.

Directive No. 98/44 / EC of the European Parliament and the Council of the European Union on the legal protection of biotechnological inventions[10] occupies a special place in the secondary law of the European Union with regard to patent protection of inventions. The Directive refers to the purposes of patenting industrial, commercial, scientif-

[6] Regulation (EU) no 1257/2012 of the European Parliament and of the council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0001:0008:en:PDF (accessed 23.04.2023).

[7] Council Regulation No. 1260/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0089:0092:en:PDF (accessed 23.04.2023).

[8] Agreement on a Unified Patent Court. (2013, 20 June). Official Journal of the European Union, C175. Available at: https://www.unified-patent-court.org/sites/default/files/upc_documents/agreement-on-a-unified-patent-court.pdf

[9] Leder, P. & Stewart, T. A. (1986). Method for producing transgenic animals. Patent No. EP0169672A1.. Available at: https://patents.google.com/patent/EP0169672A1/en

[10] Eur-Lex. (1998). Directive No. 98/44/EC of the European Parliament and of the Council of the European Union on the legal protection of biotechnological inventions. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044 (accessed 22.03.2023).

ic, diagnostic, therapeutic biotechnology. Its provisions are intended to protect the dignity and integrity of the human being. In spite of the fact that the human body and its parts are not patentable, inventions based on elements isolated from the human body may be patented.

The Directive allows the patenting of genes. 'DNA sequences isolated from their environment became patentable, as long as this was deemed to constitute an "industrial product" and not merely a natural substance' (Bergel, 2015). Opponents of the Directive pointed out that the patenting of genes infringes human dignity, turning the individual from a subject into an object of legal relations.

This Directive establishes an indicative list of non-patentable inventions, in particular, processes that change the genetic identity of a person contained in their germline[11]. European patents are not granted for inventions or their publication, exploitation of which is contrary to public order and morality.

The judgments of the Court of Justice of the European Union are of great importance. Thus, in Oliver Brüstle v. Greenpeace[12], the Court of Justice ruled that any cell derived from a human embryo has the ability to develop into a human (including a fertilized egg, an un-fertilized egg in which a nucleus has been placed, an unfertilized egg that has been stimulated to divide and develop), and is not patentable. In addition, the Court of Justice also held that the use of such a cell for research does not make it patentable. Such an invention is not considered to be patentable, including in cases where it requires the destruction of a human embryo or its use as a base material (Tkachuk, 2019).

Legislation of foreign countries

There are slight differences in the rules for granting patents by the respective filing offices, but the basic grant criteria are generally the same all over the world.

The invention must be patentable subject matter. Patentability criteria include: novelty; compliance with a certain inventive step (i.e. the invention should not be obvious); and possibility of industrial application (utility). Moreover, the patent must describe the invention in sufficient detail, in such a way that 'a person skilled in the art' can make and use it without additional experimentation. Despite the similarity of international approaches in establishing common patent criteria, their interpretation and application often differ in various jurisdictions.

Genome-related research is an area in which the interpretation and implementation of the criteria for granting patents differ to a large extent.

The first patents for DNA were issued in the 1970s, but their number increased dramatically in the mid-1990s when patentable inventions began to appear in large numbers.

[11] Eur-Lex. (2011). Judgment of the Court (Grand Chamber) of 18 October 2011. Oliver Brüstle v Greenpeace eV. Reference for a preliminary ruling: Bundesgerichtshof - Germany. Directive 98/44/EC - Article 6(2)(c) - Legal protection of biotechnological inventions - Extraction of precursor cells from human embryonic stem cells - Patentability - Exclusion of 'uses of human embryos for industrial or commercial purposes' - Concepts of 'human embryo' and 'use for industrial or commercial purposes'. Case C-34/10. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62010CJ0034 (accessed 11.05.2023).

[12] Case C-34/10, Oliver Brüstle v Greenpeace eV. European Court Reports, 2011, I-09821. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62010CJ0034 (accessed 11.05.2023).

Legislative acts regulating copyright protection for developments in the field of genomic research at the national level are now of interest. The first state under consideration is Brazil. Brazil was a founding member of the 1883 Paris Convention for the Protection of Industrial Property and the fourth country in the world to adopt a law regulating patenting.

On May 14, 1996, Brazil passed Law No. 9.279[13] on Industrial Property, aimed at fulfilling Brazil's obligations under the TRIPS Agreement (the introduction of minimum patent standards). In 1998, the Law on Copyright and Related Rights, and in 2015, Law No. 13.123 governing access and benefit-sharing of genetic resources and associated traditional knowledge were introduce[14]. Under current Brazilian law DNA is not patentable. Article 18, paragraph III, article 10, paragraph IX, Law No. 9.279 indicate that genes should not be considered as patentable objects. On the other hand, the law allows chemical products to be patented, if they meet the criteria of novelty, inventive activity and industrial application.

In 1962, the Science Foundation of the State of São Paulo (FAPESP) was established in Brazil. In 1997, FAPESP set up the Organization for Nucleotide Sequencing and Analysis (ONSA), a virtual community of 35 laboratories throughout the state. ONSA's first project was to sequence the genome of a bacterium which infects all varieties of the sweet orange (the bacterium's damage to Brazilian orange growers is estimated at about $100 million a year). The successful sequencing of the genome of the X fastidiosa bacterium led to the sequencing of genes associated with human diseases (Simpson et. al., 2000). The team of scientists received international recognition which led to the attraction of foreign investors to finance human-related sequencing projects. The genome of X fastidiosa was the first complete sequence obtained by sequencing a plant disease organism. The FAPESP experience is of interest to the international community, since a virtual research association was established. FAPESP's Charter forbids it from assembling its own corps of scientists. Thus, it is an investment of existing centers in the region, rather than an accumulation of resources by a small group of researchers. This has led to the exchange of knowledge between a large number of researchers and sustainable investment in the industry. The virtual network strategy has enabled ONSA to maximize the return on FAPESP funding, overcome geographic silos, and produce a significant number of high-quality geneticists. The success of the X fastidiosa project has advanced Brazil to the international level. ONSA has also established international contacts. For instance, ONSA is sequencing genes associated with human cancer in collaboration with the Ludwig Institute in Switzerland (Konde, 2009). In 2000, the Brazilian government advanced the São Paulo Genome Project at the national level.

The experience of Indian legal regulation is also noteworthy. The rapid development of information technology, the training of a large staff of scientists and the dynami-

[13] WIPO. (1996). Brazil. Law No. 9.279 of May 14, 1996 (Law on Industrial Property, as amended up to Law No. 10.196 of February 14, 2001). Available at: https://www.wipo.int/wipolex/en/legislation/details/17626

[14] WIPO. (1998). Brazil. Law No. 9.610 of February 19, 1998 (Law on Copyright and Neighboring Rights, as amended by Law No. 12.853 of August 14, 2013). Available at: https://wipolex.wipo.int/ru/legislation/details/17474

cally advancing pharmaceutical industry (primarily the production of generics) contribute to the international recognition of the biotechnology in India.

The Patents Act of India was passed in 1970[15], the Copyright Act – in 1957[16].

An amendment to the Patents Act, passed in 1999, was intended to provide temporary patent protection as a step towards full TRIPS compliance, through the exercise of exclusive marketing rights (EMR). EMRs grant exclusive rights to sell patented products, while full product patents grant exclusive rights to both manufacture and sell products. The term of EMR protection is five years.

The 1999 Amendment made it possible to file applications for products, including substances intended for use or which can be used as a drug or medicinal product. However, they exclude an intermediate for the preparation of a drug. The 2003 Amendment included provisions to extend the term of a patent to 20 years and provisions to protect public health. In order to protect indigenous knowledge, an exemption was granted for products based on Indian systems of medicine. Section 3 of the Patents Act provides that an invention which is in fact indigenous knowledge representing traditional knowledge is not subject to patenting. Indian law also does not allow the granting of patents for genes or cells (Chapter II of the Patent Act).

The Department of Biotechnology was established by the Government of India in 1986. The Department established a program on human genetics and genomic analysis, which includes projects in the fields of genetic diagnosis and counseling, functional genomics, human genome diversity and biotechnology. There are Genetic Diagnosis and Counseling Departments throughout India which provide genetic testing and counseling services to patients suffering from genetic diseases such as thalassemia, Duchenne muscular dystrophy, hemophilia and cystic fibrosis, etc. (Mallick, Chandra, & Samal, 2015). In 1986, the Department set up a bioinformatics program. This program then led to the Biotechnology Information System Network which operates throughout India. Nowadays, India can be called a major regional hub for genomic data banks and networks. The Center for Plant Genomics in New Delhi and the Center for Human Genetics in Bangalore were established.

In a number of states, national legislation does not contain provisions (or such provisions are not unambiguous, require clarification, or may be interpreted in different ways) regarding the legal protection of intellectual property rights for inventions in the field of genome (Brody, 2006). In such cases the judicial practice becomes of particular importance. This applies to the states governed by the Anglo-Saxon legal system (USA, Australia, Canada and others), where the courts, in fact, are vested with the right to make laws, especially given the existing gaps in regulation (Ponomareva, 2019).

The United States grants many more patents based on DNA sequences than other states. In April 2009, the US Patent and Trademark Office (USPTO) issued the 50,000th US patent, included in the Georgetown Univer-

[15] WIPO. (1998). Brazil. Law No. 13.123 of May 20, 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge). Available at: https://wipolex.wipo.int/ru/legislation/details/15741

[16] WIPO. (1957). India. The Copyright Act, 1957 (Act No. 14 of 1957, as amended up to Act No. 33 of 2021). Available at: https://wipolex.wipo.int/ru/legislation/details/15814

sity DNA Patent Database. This database includes patents that mention terms specific to nucleic acids (e.g. DNA, RNA, nucleotide, plasmid, etc.)[17]. The specific nature of many of the terms unique to nucleic acid structures makes it possible to track patents which are largely consistent with and are the result of genomic research.

The most significant of the US court cases related to the patenting of DNA, as well as processes for their isolation or changes, include:

John Moore v. University of California[18]. A cancer cell line, which was subsequently patented, was obtained from the removed spleen of John Moore. All Moore's attempts to challenge the grant of the patent were rejected by the court as unfounded.

Diamond v. Chakrabarti[19]. The application concerned the patenting of a bacterium bred for the processing of petrochemical products and intended to eliminate the consequences of oil spills. The US Supreme Court ruled that this invention is subject to patent protection, since living organisms can be patented if they have been modified by humans (Dorn, 2001).

The Association for Molecular Pathology vs Myriad Genetics case[20] became a turning point in determining the criteria for patentability of DNA. Myriad Genetics identified and isolated for the first time the BRCA1 and BRCA2 genes responsible for diagnosing an increased risk of breast and ovarian cancer (Etheridge, 2005). The company applied for patents for both isolated BRCA genes and complementary DNA (cDNA), a synthesized product that reflects the coding regions of BRCA genes, and primers used in diagnostics. In addition to AMP (Association for Molecular Pathology) and the University of Pennsylvania, other plaintiffs in the lawsuit included researchers from Columbia, Emory and Yale, a number of patient advocacy associations and several patients.

Clinical pathologists have been particularly concerned about the issuance of patents on genes, since their medical practice consists of providing clinical diagnostic services and is affected by intellectual property rights. The University of Pennsylvania Genetic Diagnostics Laboratory has been advised to stop and refrain from testing patient samples for the BRCA sequence, since such testing infringes Myriad Genetics' patent rights.

The Court of First Instance ruled that both isolated DNA and synthetically generated complementary DNA (cDNA) were patentable. The Supreme Court reversed the ruling in part, holding that only synthetically engineered cDNA does not occur naturally, so only it meets the patentability requirements.

In Greenberg vs Miami Children's Hospital Research Institute[21] case, parents of children with Canavan disease provided biological sam-

[17] WIPO. (1957). India. The Copyright Act, 1957 (Act No. 14 of 1957, as amended up to Act No. 33 of 2021). Available at: https://wipolex.wipo.int/ru/legislation/details/15814.

[18] Justia US Law. (1990). Moore v. Regents of the University of California (1990). Available at: https://law.justia.com/cases/california/supreme-court/3d/51/120.html

[19] Justia US Law. (1980). Diamond v. Chakrabarty, 447 U.S. 303 (1980). Available at: https://supreme.justia.com/cases/federal/us/447/303/

[20] Justia US Law. (2013). Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013). Available at: https://supreme.justia.com/cases/federal/us/569/576/

[21] United States District Court, S.D. Florida, Miami Division (2003). Greenberg v. Miami Children's Hospital Research Institute. West's federal supplement, 264, 1064–1078.

ples of their children and financial support for research in the hope of learning about the disease and finding treatments. They also helped to find and recruit other parents whose children suffer from Canavan disease (Lekovic, 2004). A number of non-profit organizations contributed to the formation of an information registry for this disease. Ruben Matalon identified the gene responsible. Later, without notifying the families concerned, he applied for a patent on the sequence he had deciphered. After receiving the patent, Matalon and the Miami Children's Hospital (the place where the research was conducted) began to limit any activities related to the research and modification of the gene responsible for the progress of Canavan disease. Greenberg, along with other families, filed a lawsuit against the physician and the Miami Children's Hospital. The claims were based on arguments that the defendants did not obtain the informed consent of patients to conduct research on their biomaterials and subsequent commercial use; they had received unjust enrichment by deliberately concealing the intention to commercialize the results of research. Illegally, under the guise of a trade secret, they had limited research and made it impossible to find funds for diagnosing and supporting sick children. According to the plaintiffs, all genetic materials, as well as financial support were provided to Matalon solely for the purpose of identifying mutations in the gene that caused the disease and the subsequent development of special tests. The plaintiffs sought an indefinite injunction to enforce patent rights over the Canavan gene sequence. The court ruled that all plaintiffs' claims (with the exception of unjust enrichment) should be dismissed due to the fact that informed consent should not contain the specific purpose of the research. Otherwise this could lead to each of the patients being able to control the use of the results and thus hinder the development of science. The judicial body decided that participants in genomic research had no property rights to genetic information and did not have the right to demand termination of a certain type of use, if such use was not provided at the time of the presentation of biological samples. The court also did not support the position of the plaintiffs that the database contained genetic information relating to their individuality, and they, accordingly, could control the use of such information. The court concluded that biological samples are not recognized as the property of the patient, which means that genetic information does not imply the presence of any of their property interests.

In *Ariosa Diagnostics vs Sequenom,* Inc.[22], the Court ruled that 'one who discovers a hitherto unknown phenomenon of nature cannot claim a monopoly… A process or method is not patentable simply because it involves only laws of nature, natural phenomena, or abstract ideas'. The most important condition for patentability is the presence of an element (or set of elements) that constitutes an inventive step that is not limited to 'the mere introduction of additional procedures defined in an overly generalized and abstract way,' as the US Supreme Court stated. Although the ***Myriad*** case dealt with

[22] United States District Court, S.D. Florida, Miami Division (2003). Greenberg v. Miami Children's Hospital Research Institute. West's federal supplement, 264, 1064–1078.

a combination of components, the decision also stated that 'the processes used by Myriad to isolate DNA were well known to geneticists at the time' (Merksamer, 2016). Guided by the opinion of the Supreme Court, the District court noted that if the applicant had created an innovative method for extracting DNA, this method would have been recognized as patentable. However, the methods claimed simply relied on DNA extraction processes which Sequenom acknowledges as common methods for such research.

Thus, the District Court for the Northern District of California emphasized the element of natural origin in the issue of patentability of applications and sided with the position of the Supreme Court in the Myriad case, as well as some previous cases raising the problem of determining patentability.

Plaintiffs contesting the patenting of the genes argued that the use of patents by companies like Myriad, as well as the very existence of patents in this area significantly limit the possibilities for research for specialists and negatively affect the scientific progress.

With regard to patients, there may be a situation in which research is carried out on the basis of the analysis of their genetic material, but wherein said patients are unable to use the results of such research. There is also no opportunity to refer to a specialist from another company for an alternative opinion. This lack of competition has kept the cost of testing high.

Judicial practice enables the tracing of the trend that has developed in the United States and other countries (for example, Australia), according to which human genes are not subject to patenting.

The role of WTO and TRIPS Agreement

The adoption of a number of acts and judgments has been accompanied by public outcry and protests related to the restrictions imposed on patented inventions. The right of everyone to enjoy the benefits of scientific progress is enshrined in a number of international agreements. Article 12 of the Universal Declaration on the Human Genome and Human Rights provides that the benefits from advances in biology, genetics and medicine concerning the human genome shall be made available to all with due regard for dignity and human rights of each individual and that the applications of research shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole. Patients who wish to benefit from the advances should be able to claim such a right.

On the one hand, this right is not inconsistent with patent protection, since patents are intended to encourage advances in biotechnology and that the benefits from them will be 'available to all' after the patent expires. On the other hand, in the case of serious illnesses, there is no time to wait.

The TRIPS Agreement states that 'the protection and enforcement of intellectual property rights shall contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual benefit of producers and users of technological knowledge, and in such a way as to promote social and economic well-being, as well as a balance of rights and obligations'. Article 30 provides that restrictions on the exclusive rights granted by a patent may be established, provided that such exceptions, without good reason, do not conflict with the normal use of the patent and do not unreasonably prejudice the legitimate interests of the patent owner and consider the interests of third parties. One such limitation is the compulsory license. It allows

the limitation of access to essential medicines to be resolved by producing affordable analogues and creating technologies for conducting genetic tests, etc. (Rothstein, 2018).

A compulsory license, as a rule, provides for the payment of monetary compensation to the patent owner and may be issued to one or more individuals.

It should be emphasized that TRIPS Agreement previously provided for the issuance of compulsory licenses in the event of the abuse of patent rights, including nonuse of the invention by the patent owner. A number of states, influenced by concerns about drug patenting and, subsequently, genetic testing for breast cancer, long QT syndrome, and other diseases, have included compulsory license provisions in their national legislation. France and Belgium have created compulsory licensing bodies. Canada passed the Patents Act which introduced a compulsory licensing procedure. The Brazilian Patent Law No. 9.279 and the Indian Patent Law of 1970 also allow for the issuance of compulsory licenses.

Significant contributions to the establishment of unified mechanisms for the protection of intellectual property rights, and the solution of problems in the field of healthcare, have been made by the World Health Organization, the World Intellectual Property Organization, and the World Trade Organization. The provisions elaborated under the WTO TRIPS Agreement are applied in accordance with the Global Strategy of the World Health Organization. Art. 31 of TRIPS Agreement provides that a compulsory license may be issued in the presence of a state of emergency or other circumstances of extreme necessity. The Agreement does not contain any criteria or signs of such a situation. Therefore, each WTO Member independently determines the grounds for issuing a compulsory license. The requirements for the presence of an emergency situation or circumstances of extreme necessity, as well as for use in the territory of the state, if the compulsory license is issued in connection with the violations of competition law, do not apply.

The practice of applying the TRIPS Agreement and national acts of the WTO member states is attracting considerable interest. In 2001, the United States filed a complaint with the WTO alleging that Article 68 of Brazilian Patent Law No. 9.279 violated Articles 27 and 28 of TRIPS Agreement. Article 68 allows Brazil to issue a compulsory license to a local manufacturer, if the patentee has not started manufacturing the product in Brazil within three years. This measure is designed to stimulate technology transfer, develop the generics industry and ultimately provide patients with access to life-saving medicines. Compulsory licenses are issued not only for drugs, but also for genetic tests or other inventions in the field of genomic research.

A number of acts have been passed within the framework of close cooperation between the WHO, WIPO, and WTO. They take into account their role in establishing and maintaining the relationship between public health, the intellectual property system, international trade and competition rules, as well as measures aimed at stimulating innovation and increasing the availability of genomic technologies. Such acts include: the WTO Doha Declaration on the TRIPS Agreement and Public Health; the WHO and the WTO Joint Research 'WTO Agreements and Public Health'; the introduction of the TRIPS Agreement flexibilities designed to ensure the availability of medicines for

countries which do not have their own capacities for their production; Report of the WHO Commission 'Public Health, Innovation and Intellectual Property Rights'; and Adoption of the WHO 'Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property', inter alia.

We should also mention the formation of active trilateral cooperation between the WHO, WIPO and the WTO in this area. The international regulation of patenting methods and results of genomic research establishes opportunities for the economic use of such achievements. Two main current trends can be summarized as follows: the human genome is the heritage of mankind; the perception of the human genome only from a utilitarian point of view, is a useful set calculated to be beneficial.

In national law, the development of legislation in this area is influenced by a variety of economic, historical and cultural factors. Unifying factors for states can be seen in the desire to establish a national biotechnological industry with the implementation of projects reflecting regional needs and requirements, and participation in international cooperation within the framework of international organizations.

Legal issues of national regulation (on the example of the Russian Federation)

The issues inherent in different national legal systems include issues related to DNA patenting; and methods for implementing genomic research.

Research by Russian scientists caused a strong reaction in the media and the medical community (Rebrikov, 2016), although it might not have been as popular as the work of Chinese scientist He Jiankui, whose research resulted in the birth of twin girls conceived through in vitro fertilization. Their DNA was modified using the CRISPR / Cas9 method in order to create immunity to the HIV virus (the girls' father was infected with HIV). Then, according to He Jiankui's statement, the opinions of the scientific community were divided. A number of scientists, including those who made a significant contribution to the development of this technology, called for a moratorium on editing the human genome in clinical practice for a five-year period without extending it to editing the genome of an embryo for research purposes (provided that the embryo is not implanted in the uterus, as well as editing the genome in human somatic cells for the treatment of diseases). Accordingly, the legislation of a number of states contains provisions that methods for cloning a person and his/her clone are not subject to patenting. This also includes methods for modifying the genetic integrity of human germline cells. Just like He Jiankui, Russian scientists tried to patent the results of their research. However, their applications were rejected.

Current Russian legislation, in particular, Part 4 of the Civil Code of the Russian Federation of December 18, 2006 N 230-FZ (hereinafter referred to as the Civil Code of the Russian Federation) contains articles 1349, 1350. In accordance with Art. 1349 of the Civil Code of the Russian Federation, methods of cloning a person and his/her clone are not subject to patenting, not are the methods for modifying the genetic integrity of human germline cells, use of human embryos for industrial and commercial purposes and methods contrary to the public interest, the principles of humanity and morality.

Russian law has not yet developed an unambiguous approach to the issues of patenting the results of genetic technologies.

The Civil Code of the Russian Federation does not contain direct prohibitions on patenting genes, methods of treatment and diagnostics (Kubyshkin & Kosilkin, 2021).

Challenging the decisions of the Federal Service for Intellectual Property (hereinafter referred to as ROSPATENT), Russian scientists referred to the fact that the proposed invention is not a method for modifying the genetic integrity of human germline cells, since a human embryo does not contain germline cells (only their predecessors) up to the gastrula stage (fourteen days). However, DNA editing, according to the proposed method, occurs at the stage of a single cell (zygote) even before the start of the cleavage process, as a result, it cannot affect human germline cells. According to the researchers, the presence of protective mechanisms and barriers is also an important factor.

One such mechanism is the system safety check model developed by Russian researchers, according to which the original genome of gamete donors is compared to the genome of the edited embryo using a special bioinformatics approach (Stein, 2019).

Barriers in this field are primarily reflected in the current legislation. In addition to protecting the rights of patients, preventing the use of drugs and methods with unproven efficacy or that can harm the patient, such barriers prevent the prompt response to the rapidly changing market for innovative research and technologies. For instance, according to Rebrikov & Tarasov (2016), it has become impossible (or possible with a delay of 3-5 years) to use most of the innovative medical methods and equipment elaborated under grants and government assignments in clinical practice. This is due to the provisions of Federal Laws 'On the fundamentals of protecting the health of citizens in the Russian Federation' dated November 21, 2011 No. 323-FZ and 'On amendments to certain legislative acts of the Russian Federation in terms of countering the circulation of counterfeit, substandard and unregistered medicines, medical devices and counterfeit dietary supplements' dated December 31, 2014 No. 532-F3. The legislative gaps include: 1) tests for rare diseases, for the diagnosis and treatment of which serial production and registration of medical devices are not economically feasible, and 2) innovative technologies in the first years of their practical application when their effectiveness, safety and clinical significance have already been proven, but serial production and registration as medical devices have not yet been completed (it usually takes about 5 years). At the same time, the entry of such developments into the market may be hampered by the lack of commercial interest of manufacturing companies to register a device in this jurisdiction (Rebrikov & Tarasov, 2016).

The enactment of ethical codes and definition of the status and composition of ethical committees are important. To date, not all medical institutions are required to establish such committees, and their activities are primarily related to the conduct of clinical trials of drugs and clinical trials of medical devices as well as a number of other areas.

In accordance with the Model Law 'On the Protection of Human Rights and Dignity in Biomedical Research in the CIS Member States', ethical review plays an important role in ensuring human rights. This act establishes standards, principles, rules, tasks for the implementation of ethical review by the Ethics Committee (e.g., the basis of ethical review includes the principles of independence, competence, non-directiveness and openness). Article 17 sets out the procedure for exercising control and oversight functions in relation

to the Ethics Committee by the competent authorities.

The powers of local ethics committees need to be expanded and clearly articulated. Additional requirements for the composition and the status of national medical chambers also need to be defined. Today, most local ethics committees include only representatives of the medical community, so the inclusion of a specialist in the field of law may also be considered. National medical chambers are usually associations of representatives of the professional community. As a rule, members of such communities have significant achievements in the professional field.

Since a unified approach to patenting the results of genomic research has not yet been elaborated, the criteria for patentability of the results of genomic research, the boundaries of exclusive rights and the conditions for issuing a compulsory license are not specified. Measures should be taken to advance a multi-level system of legislation supplementing the existing legal acts with a number of by-laws, enabling a more rapid response to the rapid development of science.

Conclusion

On the one hand, patenting and trade, including international trade, favor the transfer of technology and the commercialization of the results of genomic research. On the other hand, it can lead to a number of violations of fundamental human rights. The development of science for the benefit of patients, the absence of excessive administrative pressure on researchers, proper control of the safety of the research, verification of their admissibility both from a moral and ethical point of view, as well as the precautionary principle will provide assistance to patients without wasting time on compliance with overly formal requirements (which is especially important when providing assistance to pregnant women and children) and contribute to the advancement of science. This issue should be given special attention.

REFERENCES

Bergel, S.D. (2015). Patentability of human genes: the conceptual differences between the industrialised and Latin American countries. *Journal of Community Genet*, 6(3), 321–327. https://doi.org/10.1007/s12687-015-0228-2

Brody, B. (2006). Intellectual property and biotechnology: the U.S. internal experience. Part I. *Kennedy Institute Ethics Journal*, 16(1), 1–37. https://doi.org/10.1353/ken.2006.0002

Defossez, D.A.L. (2017). Global regulation of international intellectual property through Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): the European Union and Brazil. *Journal of Law and Regulation*, 3(2), 131–160. Available at: https://periodicos.unb.br/index.php/rdsr/article/view/19181/17701

Dorn, B.R. (2001). Chakrabarty in the Era of Genomics: Diamond v. Chakrabarty. *Journal of Technology Law & Policy*, 6(1), 101–107. Available at: https://scholarship.law.ufl.edu/jtlp/vol6/iss1/4

Ellyne, E. (2014). European unitary patent: are we there yet?. *Queen Mary Journal of Intellectual Property*, 4(1), 57–78. https://doi.org/10.4337/qmjip.2014.01.03

Erstling, J., & Boutillon, I. (2005). The Patent Cooperation Treaty: at the center of the international patent system. *William Mitchell Law Review*, 32(4), 1583–1601. Available at: https://open.mitchellhamline.edu/wmlr/vol32/iss4/9

Etheridge, J. (2005, February 9). Europeans Claim Victory in BRCA1 Gene Patent Battle. *BIOWORLD*. Avaliable at: https://www.bioworld.com/articles/386407-europeans-claim-victory-in-brca1-gene-patent-battle?v=preview (accessed 24.02.2023).

Konde, V. (2009). Secrets to Developing a Successful Biotechnology Industry: Lessons from Developing Countries. *Asian Biotechnology and Development Review*, 11(3), 11–33. Available at https://ris.org.in/sites/default/files/article2_v11n3.pdf.

Kubyshkin, A. V. (2021). Contemporary Challenges and Legal Regulation of Genome Research: Some Considerations. *Kutafin Law Review*, 8(1), 36–67. https://doi.org/10.17803/2313-5395.2021.1.15.036-067

Kubyshkin, A.V., & Kosilkin, S.V. (2021). International Legal Regulation of Genetic Research and Implementation of International Legal Standards in this sphere into Russian Legislation. *RUDN Journal of Law*, 25(1), 107–125. https://doi.org/10.22363/2313-2337-2021-25-1-107-125. (In Russ.).

Lekovic, G.P. (2004). Genetic Diagnosis and Intellectual Property Rights: A Proposal to Amend the Physician Immunity Statute. *Yale Journal of Health Policy, Law, and Ethics*, 4(2), 275–304. Available at: https://digitalcommons.law.yale.edu/yjhple/vol4/iss2/2.

Mallick, A., Chandra, S.S., & Samal, A.C. (2015). An Overview on Indian Patents on Biotechnology. *Recent Patents on Biotechnology*, 9(3), 98–213. https://doi.org/10.2174/1872208310666160325113553

Merksamer, P. (2016). Ariosa Diagnostics v. Sequenom: Metastasis of Mayo and Myriad and the Evisceration of Patent Eligibility for Molecular Diagnostics. *Berkeley Technology Law Journal*, 31(2), 495–534. Available at: https://www.jstor.org/stable/26377763

Ponomareva, D.V. (2019). Patenting of Human Genes: The United States, Canada and Australia Case Law. *Actual Problems of Russian Law*, (9), 166–173. https://doi.org/10.17803/1994-1471.2019.106.9.166-173. (In Russ.).

Rebrikov, D.V, & Tarasov, V.V. (2016). Translational medicine: untranslated regions and the stop codons. *Bulletin of RSMU*, (6), 4–9. https://doi.org/10.24075/brsmu.2016-06-01

Rebrikov, D.V. (2016). Human genome editing. *Bulletin of RSMU*, (3), 4–14. https://doi.org/10.24075/brsmu.2016-03-01

Rothstein, M. A. (2018). Time to End the Use of Genetic Test Results in Life Insurance Underwriting. *Journal of Law, Medicine & Ethics*, 46(3), 794–801. https://doi.org/10.1177/1073110518804243

Simpson, A.J, Reinach, F.C, Arruda, P., Abreu, F.A, Acencio, M., Alvarenga, R., … Setubal, J.C. (2000). The genome sequence of the plant pathogen Xylella fastidiosa. The Xylella fastidiosa Consortium of the Organization for Nucleotide Sequencing and Analysis. *Nature*, 406(6792), 151–159. https://doi.org/10.1038/35018003

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 the Kutafin Moscow State Law University*, (4), 138–145. (In Russ.). https://doi.org/10.17803/2311-5998-2019-56-4-138-145

INFORMATION ABOUT THE AUTHORS:

Maria V. Nekoteneva, Candidate of Legal Sciences, Associated Professor of the Integration and European Law Department, Senior Researcher at the Center for Law and Bioethics in the Field of Genomic Research and the Application of Genetic Technologies at the Kutafin Moscow State Law University (MSAL), Moscow, Russian Federation

Daria V. Ponomareva, Candidate of Legal Sciences, Associated Professor of the Legal Practice Department, Senior Researcher at the Center for Law and Bioethics in the Field of Genomic Research and the Application of Genetic Technologies at the Kutafin Moscow State Law University (MSAL), Moscow, Russian Federation

ИНФОРМАЦИЯ ОБ АВТОРАХ:

Мария В. Некотенева, кандидат юридических наук, доцент кафедры интеграционного и европейского права, старший научный сотрудник Научно-образовательного центра права и биоэтики в сфере геномных исследований и применения генетических технологий Университета имени О.Е. Кутафина (МГЮА), Москва, Российская Федерация

Дарья В. Пономарева, кандидат юридических наук, доцент кафедры практической юриспруденции, старший научный сотрудник Научно-образовательного центра права и биоэтики в сфере геномных исследований и применения генетических технологий Университета имени О.Е. Кутафина (МГЮА), Москва, Российская Федерация