TO THE QUESTION ABOUT THE POSSIBILITY OF PATENTING HUMAN GENES: EXPERIENCE OF LEGAL REGULATION IN RUSSIA AND FRANCE[1]

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Abstract. *The article considers the problem of patenting human genes, encouraging the development of scientific inventions in the commercial field, the increase of investment attractiveness of research. It provides cases of these problems and the main approaches to solving them from the legal point of view.*

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Currently, the problem of patenting human genes is gaining significant relevance. It is enough to give an example of the United States of America, where about 20% of human genes are patented. The need to patent human genes is obvious. It has a number of goals: to be able to research genes without taking into account competition from other organizations, to encourage the development of scientific research in the commercial sphere, and to increase the investment attractiveness of scientific research.[2]

However, the patenting of genes can also cause problems, in particular, associated with a sufficiently long period of protection of the genome sequence, which theoretically and practically can hinder the development of genomic research, creating obstacles to work with patented genetic material.

The possibility of patenting a human gene from a moral and ethical point of view is also ambiguously defined. If in some countries (the USA, Australia, China, etc.) we can find examples of court decisions that "give the go-ahead" for patenting a human gene, then in the member States of the European Union there is a noticeable trend of resistance to patenting human genes.

One such example is the legislation of one of the European Union member States, the French Republic. The legal framework for regulating relations with regatd to patenting, including biotechnologies, is made up of acts adopted at two levels: supranational and national. At the national level, patenting is regulated by the European Patent Convention of 1973[3] and Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions.[4] The national level is

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[2] *Пономарева Д.*В. Патентование человеческих генов: судебная практика Соединенных Штатов Америки, Канады и Австралии // Актуальные проблемы российского права. 2019. № 9. С. 166-173.

[3] An updated version of this document was adopted in 2007. For more information, see the Official website of the European patent office URL: https://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma1.html

[4] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions // OJ L 213, 30.7.1998, p. 13-21

represented by the French law "On patents", which largely implemented the provisions of the above-mentioned Directive, although with some adjustments.[5]

The features of the French (European) patent system in relation to the possibility of patenting human genes can be reduced to the following main characteristics:

1. In accordance with the abovementioned French law, the division of elements of a biological organism into patentable and non-patentable and the "transformation" of a discovery into an invention is due to the isolation of such elements from their natural environment and/or their production through a technological process (i.e., the possibility of patentability is determined through the prism of deciding whether a gene is isolated or not);

2. At the national level, the French legislature prohibits the patenting of gene sequences, allowing only the patenting of ways of their industrial application (in order for the criterion of industrial applicability to be considered fulfilled, it is necessary, while applying for patenting a sequence or partial sequence of a gene that produces a protein or part of a protein, to indicate which protein or part of a protein this sequence or partial sequence of a gene produces or what function it performs. A single gene sequence without specifying its function does not contain technical information and therefore is not a patentable invention).

3. The French legislature has provided for exceptions to patentability on grounds of morality and public order (inventions whose commercial use is contrary to public order and morality cannot be patented). Article 6, paragraph 2, of the French patent law also contains a non-exhaustive list of inventions that cannot be patented on grounds of public order and morality:

— human cloning processes;
— processes that change the genetic identity of a person, contained in his germ line;
— use of embryos for commercial and industrial purposes;
— processes for changing the genetic identity of animals that are likely to cause them suffering without bringing significant benefits to humans and animals, as well as the animals themselves that are the result of such processes.

Since biotechnologies are also developing intensively in the Russian Federation, and since the practical use of research results in the field of biotechnology has become a means of market policy, it is interesting to analyze the compatibility of the Russian and French approaches to the possibility of patenting human genes.

It should be noted that for the Russian Federation there are several peculiarities in the subject composition of patent holders of biotechnologies. First, according to the total number of protection documents issued by Rospatent (the Federal Executive authority responsible for issuing patents), the number of patents owned by foreign patent holders is almost three times higher than the number of patents issued to Russian applicants. Secondly, in Russia, the majority of patents for biotechnologies belong to

[5] Report from the Commission to the European Parliament and the Council - Development and implications of patent law in the field of biotechnology and genetic engineering / COM/2002/0545 final URL: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX-:52002DC0545:EN:HTML

state-owned enterprises, and the Russian Federation is the co-owner of such patents, which significantly hinders the development of biotechnologies.[6]

In accordance with Russian legislation (part IV of the Civil code of the Russian Federation)[7] for a biotechnology to be recognized as patentable, it must meet the patentability criteria of novelty, inventive step and industrial applicability.

There is a great controversy about whether biotechnology meets the novelty criterion, since a number of existing natural products are similar to biotechnologies.

When checking whether biotechnology meets the "novelty" criterion, the expert must identify whether such genes were "natural", long known to the community of geneticists, physicians, biologists; analyze whether science knew how to isolate such genes; determine whether the genes are artificially created. It seems that the modification of natural human genes is contrary to public interests, principles of humanity and morality. Meanwhile, "artificially created genes" can be patentable if they are patented for diagnostic and/or therapeutic purposes. The expert should also take into account that the introduction of artificially created genes into the human, animal or plant body in some cases can cause mutation or death of the species, which is unacceptable. Although science has known cases when the modification of individual genes, as well as elements of RNA and DNA, contributes to the treatment of a number of diseases, such as diabetes, etc.

Rospatent holds the opposite opinion to the "products of nature" doctrine. Thus, "a biotechnological product that is isolated from the environment or produced through a technical process, even if it previously existed in nature, is protectable".[8] This approach does not solve a number of problems that exist in the field of patenting biotechnologies, in particular, it concerns the patenting of transgenic animals and plants, individual cells, clones, vectors, etc.

In order to determine whether a biotechnology meets the "novelty" patentability criterion during the examination of an application, special attention should be paid to the structural and functional differences between natural objects of nature and biotechnologies, which in their isolated state are significant enough to make a noticeable difference. Structural differences from objects of nature should be understood as "significant differences in the structure, system, or location of individual parts and/or particles in the composition of biotechnology, as well as significant differences in the internal structure of biotechnology from the device of a similar object of nature". Functional differences are features associated with the manifestation of a function that differ from the features inherent in objects of living nature.[9]

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[6] *Иншакова А.*О., Рыженков А.Я., Богданова Т.Д. Правовая защита биотехнологий в РФ: преимущества патентования и критерии патентоспособности // Журнал “Legal Concept”. 2015. № 3 (28). С. 26

[7] Гражданский кодекс Российской Федерации (часть четвертая) от 18.12.2006 N 230-ФЗ // Собрание законодательства РФ. 2006.N 52 (1 ч.). С. 5496.

[8] *Иншакова А.*О., Рыженков А.Я., Богданова Т.Д. Правовая защита биотехнологий в РФ: преимущества патентования и критерии патентоспособности // Журнал “Legal Concept”. 2015. № 3 (28). С. 26

[9] See ibid.

Another criterion for patentability of biotechnology is the inventive level, in determining which an important role is played by the criterion of not being obvious to the specialist of the biotechnology specified in the application.

The non-obviousness assessment must be made directly by a specialist, taking into account the level known on the day of application submission.

When determining whether a biotechnology meets the "inventive level" criterion, it should also take into account the degree of participation of the author of the biotechnology in its creation, extraction and / or transformation, since the isolation of an object from a biological product is not yet a creation of biotechnology. However, if the author selected an object that was previously known to science, but was not isolated from the general composition of the biological product, then this action of the author will have a certain creative level and the degree of influence of the author will be obvious. In this case, the method of separating biotechnology from a biological product will be patentable in itself.[10]

The third criterion for patentability of biotechnology is industrial applicability. Here it is quite important to define the goal for which biotechnology is being developed. Practice shows that biotechnologies associated with the creation of subcellular structures (including DNA) usually pursue therapeutic and diagnostic goals. Is it always possible to create biotechnology for these purposes in accordance with Russian law?

In accordance with paragraph 4 of article 1349 of the Civil code of the Russian Federation objects of patent rights may not be:

1) methods of human cloning and its clone;
2) ways to modify the genetic integrity of human germ line cells;
3) use of human embryos for industrial and commercial purposes;
4) results of intellectual activity described in clause 1 of article 1349 of the Civil code of the Russian Federation that contradict public interests, principles of humanity and morality.

It is clear from the provisions of this article that methods of human cloning, as well as methods of modifying the genetic integrity of human germ line cells, cannot be created and/or used for any purpose. The use of human embryos is unacceptable only for industrial and commercial purposes. Although the law does not prohibit the use of human embryos for scientific purposes, it is still assumed that such use would be contrary to the public interest, the principles of humanity and morality.

What is considered contrary to the "public interest, principles of humanity and morality" remains an open question, since each of these categories requires a separate detailed research, which is of an interdisciplinary nature.

Summing up, it should be noted that the Russian legislator in relation to the possibility of patenting human genes acts in line with the practice of a number of foreign countries (in particular, the United States, Australia), which prohibits the patenting of uninsulated human DNA, but believes that it is possible to protect the patent artificially created, isolated DNA created for diagnostic, therapeutic and scientific purposes. At the same time, the norms of Russian law that affect this sphere contain a significant ethical component. The French lawmaker also tries to maintain a balance between compliance with ethical standards and freedom of scientific research. Nevertheless,

[10] See ibid.

a small, but still "victory" of the ethical component over the pragmatic scientific interest is noteworthy, since in France it is impossible to patent the DNA sequence as such, even if isolated. This conservative approach, on the one hand, may hamper scientific cooperation of states in the field of genomic research, but on the other hand will give the opportunity to think about the need to respect human rights in the context of solving controversial from ethical point of view question: is it permissible to patent a human gene or not.

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