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SOME CHARACTERISTICS OF PROTECTION OF GENE MODIFIED THROUGH GENETIC ENGINEERING

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INTRODUCTION

This article is dedicated to several features of the protection of genes modified through genetic engineering, particularly to the legal issues in intellectual property. Recent scientific findings in the field of gene engineering caused many concerns and debates not only among scientists but also among the general public. Taking into account the achievements registered in the field of biotechnology and the ongoing studies in scientific circles, as well as the new problems that have emerged, to predict the future course of developments in this field and give their legal assessment, it is necessary to have a clear idea of what modern genetic engineering is, in which directions science is developing and what possible ethical, legal and epistemological problems this development can bring.

Developments in new biological technologies, including recombinant DNA and cell fusion and monoclonal antibody technology, have raised several social and ethical questions and also give rise to problems in the field of intellectual property. The protection of genetic engineering research and its results in intellectual property continues to be the focus of discussion. Currently, the main issue discussed among lawyers is what kind of rights arise to the results of genetic activity and who has the right to possess and manage the information, processes, and results obtained during the research. These raise complex and controversial issues within intellectual property law and patent law[1]. According to the general approach, scientists performing genetic interventions should have rights to the results of scientific activities, and these rights should be protected by intellectual property law. In the framework of this work, using interdisciplinary methods of state and legal theory, as well as comparative law and formal-logical methods, we tried to answer the mentioned questions by studying the international judicial practice and legislation related to the protection of genes, including genetically modified genes, also referring to different forms of life and to the issues of patenting human genes.

Patent features of genetically modified genes

By bypassing narrow professional discussions about the content of genetic engineering[2], we should note that from a functional point of view, the essence of this

[1] See Dworkin G., Should There Be Property Rights in Genes? Philosophical Transactions: Biological Sciences, Vol. 352, No. 1357, Human Genetics: Uncertainties and the Financial Implications Ahead (Aug. 29, 1997), pp. 1077-1086 (10 pages) Published by: Royal Society, p. 1079 (https://www.jstor.org/stable/56522?seq=2#metadata_info_tab_contents, 29.07.2024)

[2] See Berg P., Baltimore D., Boyer H. W., Cohen S. N., Davis R. W., Hogness D. S., Nathans D., Roblin R., Watson J. D., Weissman S., Zinder N. D.- Potential Biohazards of Recombinant DNA Molecules; Source: Science, New Series, Vol. 185, No. 4148 (Jul. 26, 1974), p. 303 Published by: American Association for the Advancement of Science, Science (Stable URL: http://www.jstor.org/stable/1738673, 29.07.2024)

technology is the artificial construction of active genetic structures and hereditarily modified organisms. In other words, the essence of genetic engineering is the purposeful construction of special hybrid molecules outside a living organism (as it is commonly called: "in vitro"; translated from Latin means "in glass") with their subsequent introduction into a living organism [1]. Moreover, hybrid molecules (recombinant DNA) become an integral part of the genetic apparatus of the given organism. As a result, the hereditary program of the organism changes: genetic, and therefore, biochemical and physiological characteristics are transmitted to it[2].

We should note that the concept of "gene patenting", despite some impreciseness in content, is quite widespread and is used to describe patent applications for products and processes related to genes or genetic information. From the beginning, we should clarify that it is impossible to patent a gene as it exists in nature, as it is a naturally occurring gene in the human body or tissues. The mentioned circumstance is discussed in detail, especially in American judicial practice[3], where the main discussion is carried out from the point of view of the possibility and differences of patenting living organisms and inanimate natural elements. American jurisprudence has long treated biological inventions as unpatentable products of nature, but that theory had two huge exceptions for natural products; "isolated" and "purified" from their natural environment[4].

Molecular biology and intellectual property policy in this field changed significantly after a series of events in the 1980s. Namely, the discovery of recombinant DNA technology, the public sale of shares of Genetech; one of the first biotechnology companies, which led to increased interest in biotechnology and the flow of investment in the field, as well as the passage of the Bayh-Dole Act (officially known as the Amendment to the Patent and Trademark Act[5]) in the United States that provided many benefits to universities, small businesses and nonprofit research organizations, and eventually the US Supreme Court decision in "Diamond v. Chakrabarty" case[6], which was of great importance in the development of patent law in this field.

In the "Diamond v. Chakrabarty" case, one of the main exceptions to patent law was formulated and interpreted. That is, manifestations and products of nature are not protected. As a general rule, laws of nature, natural/physical phenomena, and abstract

[1] See Saltzman W. M.; Frontiers of Biomedical Engineering, Open Yale courses. The course was recorded in Spring 2008, (https://www.youtube.com/watch?v=WXGL2Kracgs, 29.07.2024)

[2] See Гончаренко Г. Г. Основы генетической инженерии. Методическое пособие /Отв.ред. Л.В. Хотылева.– Гомель: УО «ГГУ им. Ф.Скорины», 2003. – 118 с., pp. 44-46 (https://core.ac.uk/download/pdf/75998736.pdf, 29.07.2024)

[3] See Holman C. M., Gene Patents under Fire: Weighing the Costs and Benefits, book chapter in Biotechnology and software patent law: a comparative review on new developments, edited by Emanuela Arezzo and Gustavo Ghidini, Edward Elgar Publishing (2011), p. 267 (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1710150, 29.07.2024)

[4] See Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95 (1911), April 28, 1911 · United States Circuit Court for the Southern District of New York, 189 F. 95 (Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95 (1911) | Caselaw Access Project, 29.07.2024)

[5] See Bayh-Dole Act, formerly known as the Patent and Trademark Act Amendments, Federal law enacted in 1980 (https://drexel.edu/research/innovation/technology-commercialization/bayh-dole-act/#:~:text=The%20Bayh%2DDole%20Act%2C%20formerly,research%20programs%20within%20their%20organizations. 29.07.2024)

[6] Sherkow J. S., Greely H. T., The History of Patenting Genetic Material. Annual Review of Genetics, Vol. 49:161-182 (Volume publication date November 2015), First published online as a Review in Advance on October 6, 2015, p. 2 (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2325679, 29.07.2024)

ideas are not protected by patent law[1]. At the same time, however, US jurisprudence lacked a clear distinction between laws of nature, natural products, and natural/physical phenomena[2], and one of the court's interpretations of the challenged bacterial properties as "natural phenomena" can apply to all of these concepts[3].

As for abstract ideas, there is no clear position regarding this exception in US jurisprudence. According to the general approach, ideas that can be interpreted so broadly as to include natural principles, as well as ideas that involve exclusively mental processes are considered abstract. As a result, in the conditions of lack of clarity and uncertainty of the mentioned exceptions, a patent within the same case can be rejected based on being a product of nature or an abstract idea, as well as a combination of both grounds.

The European Patent Office is guided by the exceptions defined by the European Patent Convention[4]. The Convention, like the American common law, from the list of patentable objects excludes inventions, scientific theories, mathematical methods, artistic works, schemes, rules and techniques for performing mental operations, games, or business, as well as computer programs, representations of information[5].

National legislation also provides exceptions to the protection of inventions. Of the defined exceptions, the distinction between scientific discovery and invention is most important. This distinction was an essential part of the judicial act discussed above. In this case, the main distinguishing feature of the mentioned concepts is that the discovery implies the revelation of a phenomenon existing in nature without interventions and changes. The invention suggests a new, qualitative change. Therefore, objects naturally found in nature cannot be the object of patenting. At the same time, Article 12, Part 4 of the Patent Law[6] of The RA states that biological matter that has been isolated from its natural environment or produced by a technical process may be the subject of an invention, even if it previously existed in nature. It should be noted that this regulation is highly controversial and causes an internal contradiction, since biological matter separated from its natural environment also receives protection, which, in the sense of part 5 of the same article, is considered any material containing genetic information and reproducing independently or in a biological system.

To better understand the essence of the problem, we can also consider another well-known case in American judicial practice: the decision of the US Supreme Court

[1] See Mayo Collaborative Servs. v. Prometheus Labs., Inc. - 566 U.S. 66, 132 S. Ct. 1289 (2012) The Supreme Court of the United States (https://supreme.justia.com/cases/federal/us/566/66/, 29.07.2024)

[2] See Burk D. L., The Curious Incident of the Supreme Court in Myriad Genetics. Legal Studies Research Paper Series No. 2014-29, University of California, Irvine ~ School of Law The paper, pp. 510-516 (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2407094, 29.07.2024)

[3] See Funk Bros. Seed Co. v. Kalo Inoculant Co**.,** 333 U.S. 127, 130 (1948). US Supreme Court (Funk Brothers Seed Co. v. Kalo Inoculant Co.: 333 U.S. 127 (1948): Justia US Supreme Court Center, 29.07.2024)

[4] See The European Patent Convention, abbreviated as EPC, signed in Munich in October 1973 (https://treaties.un.org/doc/Publication/UNTS/Volume%201065/volume-1065-I-16208-English.pdf 29.07.2024)

[5] See Burk D. L., The Curious Incident of the Supreme Court in Myriad Genetics. Legal Studies Research Paper Series No. 2014-29, University of California, Irvine ~ School of Law The paper, pp. 510-516 (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2407094, 29.07.2024)

[6] See Patent law of The Republic of Armenia. adopted on March 3, 2021, entered into force on July 1, 2021, source: Unified website 2021.03.22-2021.04.04 Official publication date 03.31.2021,

in the "Association For Molecular Pathology Et Al. V. Myriad Genetics, Inc." case. In this case, the court ruled that naturally occurring genes are not patentable[1]. The decision addressed a specific legal theory called "object patentability" or simply "patentability". In this decision the court discussed the patent claim for two types of human genes. The first includes "isolated genomic DNA": DNA particles of various sizes extracted from the surrounding genome. The second type is the requirement for "complementary DNA (cDNA)", which is created artificially and does not occur naturally. The court confirmed that genomic DNA is not patentable even if it is "isolated and purified" from the surrounding chromosome, while the latter case is patentable. The court's decision focused on whether the two types of DNA exist in nature. Because in the first case, the court viewed genomic DNA as simply a little segment detached from a longer chromosome, the court concluded that it was more of a "product of nature" than a "product of human ingenuity." As for the second type of DNA, it does not exist in nature. Even if its nucleotide sequence is "given by nature", laboratory methods in the transcription of RNA unquestionably create a new product when the complementary DNA is formed, so the latter is patentable unless other theories preclude its protection[2]. This position is thoroughly acceptable to us. Otherwise, the foundations of intellectual property rights are also undermined, making the protection of the processes and results implemented in the field of genetic engineering illogical because the essential component, the result of human intellectual creativity, is missing.

The mentioned judicial acts formed the entire legal policy and logic of this field, becoming a benchmark for theoretical discussions not only in the United States but also in many other countries. As a result, if we discuss the current domestic regulation with the mentioned logic, we will notice that it does not derive from the essence of gene patenting and genetic engineering because biological material, including genes, is protected simply on the basis that they are separated from their natural environment. Therefore, to preserve the entire logic of patenting and to avoid further problems, it is necessary to exclude the protection of any object in its natural state as an invention.

Patentability of different life forms

Along with the general developments presented above, one of the crucial issues discussed in the late 20th century was the question of patentability of various forms of life, which implied that they should comply with the basic principles of patent law regarding innovation, utility, and non-obviousness.

In 1980, The United States Supreme Court decision[3] established that the ordinary patent can also be granted for inventions involving living organisms because the problem should be discussed not in the framework of "living organism and inanimate

[1] See Association For Molecular Pathology Et Al. *V.* Myriad Genetics, Inc., Et Al. No. 12–398. Argued April 15, 2013—Decided June 13, 2013, Supreme Court of The United States (Assoc. for Molecular Pathology v. Myriad Genetics, Inc. :: 569 U.S. 576 (2013) :: Justia US Supreme Court Center, 29.07.2024)

[2] See Sherkow J. S., Greely H. T., The History of Patenting Genetic Material. Annual Review of Genetics, Vol. 49:161-182 (Volume publication date November 2015), First published online as a Review in Advance on October 6, 2015, p. 1569 (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2325679, 29.07.2024)

[3] See Diamond v. Chakrabarty, 447 U.S. 303 (1980) No. 79-136 Argued March 17, 1980 Decided June 16, 1980 Supreme Court of The United States (https://supreme.justia.com/cases/federal/us/447/303/, 29.07.2024)

element of nature" phenomena but in the context of distinguishing "creation of nature and the result of human activity" phenomena[1].

The decision and the controversy surrounding the patenting of a genetically modified organism called the "Harvard Oncomouse"[2] led to widespread public debate and raised many practical[3] and theoretical issues, including utilitarian and John Locke's ideas on the origins of property rights for gene patenting[4].

We believe that although within the framework of John Locke's theory, the origin of intellectual property right to an object created as a result of the combination of mental activity and physical nature is justified from a natural-legal point of view, in the case of the created object being a living organism, the issue is controversial. Guided by biocentric approaches and agreeing with the Nobel Peace Prize laureate, renowned biocentrist Albert Schweitzer's view that all organisms are naturally endowed with definite internal characteristics that are useful to them, which deserve respect and protection[5], we find it most acceptable to us the Canadian courts' position that higher forms of life are not patentable. However, we are also not in favor of biocentrist egalitarianism, according to which all organisms have equal moral importance, so patents on plants and microbes are more acceptable than patents on animals.

Turning to the patentability of human genes, it is worth noting that for some critics of the modern model, DNA does not meet the legal criteria for patentability because it is more closely related to discovery than invention. Others believe that DNA sequences are not ordinary chemical compounds but chains of information, that the genome should be viewed as a vast database, and that its data should be accessible to all[6]. According to the genocentric approach, patenting human genes is not ethically acceptable because it does not consider the vital role genes play in determining human nature. Proponents of this approach argue that the gene encapsulates human nature, and no individual or organization can have control over human genetic material. This point of view, however, we believe, unreasonably combines genetic identity and human personality, perceiving a person only as a set of genes.

Bearing in mind that patents have traditionally had an economic function that predetermines the material value of the patented object, opponents of patenting,

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[1] See Wright B. D., Plant Genetic Engineering and Intellectual Property Protection. University of California. Division of Agriculture and Natural Resources p. 1-2 (https://anrcatalog.ucanr.edu/pdf/8186.pdf, 29.07.2024)

[2] See Bioethics and Patent Law: The Case of the Oncomouse. June 2006. WIPO MAGAZINE (Bioethics and Patent Law: The Case of the Oncomouse (wipo.int), 29.07.2024)

[3] See Genetic Inventions, Intellectual Property Rights And Licensing Practices. Evidence And Policies. Organisation For Economic Co-Operation And Development (OECD) 2002, pp. 10-12 (https://www.oecd-ilibrary.org/docserver/9789264034730-en.pdf?expires=1722221223&id=id&accname=guest&checksum=66895250B3B636915A05CD1D5FC408C2, 29.07.2024)

[4] See Meyer J. M., Rights to Life? On Nature, Property and Biotecnology. Government and Politics, Humboldt State University, The Journal of Political Philosophy; Volume 8, Number 2, 2000, pp., 159-162

[5] See Hettinger N., Patenting Lif atenting Life: Biotechnology e: Biotechnology, Intellectual Pr , Intellectual Property, and Environmental Ethics. 22 B.C. Envtl. Aff. L. Rev. 267 (1995), Boston College Environmental Affairs Law Review, pp. 285-286,

[6] See Genetic Inventions, Intellectual Property Rights And Licensing Practices. Evidence And Policies. Organisation For Economic Co-Operation And Development (OECD) 2002, pp. 10-12 (https://www.oecd-ilibrary.org/docserver/9789264034730-en.pdf?expires=1722221223&id=id&accname=guest&checksum=66895250B3B636915A05CD1D5FC408C2, 29.07.2024)

guided by neo-Kantian ideas, also argue that humans have an intrinsic value that cannot be quantified from an economic perspective. Therefore, seeing people as commodities with commercial value disrupts the idea of what a person is and turns all human life into a commodity.

Many authors also argue that patenting human genes is ethically impermissible since the human genome constitutes the universal heritage of all mankind. According to the arguments presented, genetic sequence information, which is the result of the human evolutionary process, should not belong to a single patent holder but to all of humanity[1].

Conclusion

We consider it necessary to point out that the arguments, including the reasoning about the creation of new forms of slavery, presented by the opponents of human gene patenting are not valid because, in this case, the patent does not imply the provision of any kind of rights to a human being, but the researcher is allowed to prevent other persons from conducting similar research outside of the human organism. The argument that patenting a human gene is patenting "life" is also refuted by the same logic because DNA is not a living being but a chemical compound that carries genetic information. Of course, a patent does not grant anyone a right to a gene that is considered the common heritage of mankind. As we have already noticed above, the isolation of a gene only from its natural environment does not imply the provision of any right to it. Rights also do not arise when the researcher simply discovers previously unknown but always existing features of the gene because, in that case, it is more about discovery and not invention. To counter the stated position it is necessary to emphasize once again the leading function of patents, which implies the establishment of a monopoly over a patentable invention for a certain period. Therefore, the fact that genes will become a patentable object does not mean that research in this field will stop. As a result, the research will continue, and the authors will not gain the necessary and sufficient protection for the discoveries made[2]. Therefore, in the conditions when genes will be obtained in compliance with the rules of medical ethics (this implies obtaining genes with the consent of a person), will be taken out of their natural environment and will receive new features that do not exist in the natural state, then if other conditions do not contradict, they may be subject to patenting as an invention.

Abstract

Development in new biological technologies, including the latest advances in genetic engineering, have raised several social and ethical issues and created problems in the field of intellectual property. Within the framework of the article, the author discussed the features of genetic engineering from a legal, ethical, and philosophical point of view, presented the content of the latter and its connection with the law, and presented the possible consequences of experiments in this field, revealed the substance of gene licensing. In particular, the author discussed the problems of patenting living organisms and human genes.

[1]See Constand S., Patently a Problem? Human Gene Patenting and its Ethical and Practical Implications, Legal Studies Research Paper No. 13/75 October 2013, Sydney Law School, pp. 12-15

[2] See Dworkin G., Should There Be Property Rights in Genes? Philosophical Transactions: Biological Sciences, Vol. 352, No. 1357, Human Genetics: Uncertainties and the Financial Implications Ahead (Aug. 29, 1997), pp. 1077-1086 (10 pages) Published by: Royal Society, p. 1079 (https://www.jstor.org/stable/56522?seq=2#metadata_info_tab_contents, 29.07.2024)

As a result of the study, the author presented her position regarding the possibility of patenting genes, including genes modified through genetic engineering, living organisms, as well as human genes, and the possible scope of rights and rights holders arising over them, outlining the scope of legal regulation of the field.

Keywords: *genetic engineering; intellectual property; patent for invention; gene patenting; genetically modified gene; patentability; living organism patent; human gene patent.*

ԳԵՆԵՏԻԿ ԻՆԺԵՆԵՐԻԱՅԻ ՄԻՋՈՑՈՎ ՓՈՓՈԽՎԱԾ ԳԵՆԻ ՊԱՇՏՊԱՆՈՒԹՅԱՆ ՈՐՈՇ ԱՌԱՆՁՆԱՀԱՏԿՈՒԹՅՈՒՆՆԵՐ

Սվետլանա Կիրակոսյան
ԵՊՀ պետության և իրավունքի տեսության ու պատմության ամբիոնի ասպիրանտ
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Համառոտագիր

Կենսաբանական նոր տեխնոլոգիաների զարգացումը՝ ներառյալ գենային ինժեներիայի ոլորտում արված վերջին ձեռքբերումները, բարձրացրել են սոցիալական և էթիկական մի շարք հարցեր և ստեղծել խնդիրներ նաև մտավոր սեփականության ոլորտում: Հոդվածի շրջանակներում հեղինակը քննարկել է գենային ինժեներիայի առանձնահատկությունները իրավական, էթիկական և փիլիսոփայական տեսանկյունից, ներկայացրել վերջինիս բովանդակությունը և կապը օրենքի հետ, այս ոլորտում իրականացվող գիտական փորձարկումների հնարավոր հետևանքները և բացահայտել գեների արտոնագրման էությունը: Մասնավորապես՝ հեղինակը քննարկել է կենդանի օրգանիզմների և մարդկային գեների արտոնագրման հիմնախնդիրները:

Հետազոտության արդյունքում հեղինակը ներկայացրել է իր դիրքորոշումը գեների, այդ թվում՝ գենային ինժեներիայի միջոցով փոփոխված գեների, կենդանի օրգանիզմների, ինչպես նաև մարդկայն գեների արտոնագրման հնարավորության և դրանց նկատմամբ ծագող իրավունքների և իրավատերերի հնարավոր շրջանակի վերաբերյալ՝ ուրվագծելով ոլորտի իրավակարգավորման շրջանակը:

Բանալի բառեր – *գենետիկ ինժեներիա; մտավոր սեփականություն; գյուտի համար տրվող արտոնագիր; գեների արտոնագրում; գենետիկ ինժեներիայի միջոցով փոփոխված գեն; արտոնագրաունակություն; կենդանի օրգանիզմի արտոնագրում; մարդկային գեների արտոնագրում:*

НЕКОТОРЫЕ ОСОБЕННОСТИ ЗАЩИТЫ ГЕНОВ, МОДИФИЦИРОВАННЫХ С ПОМОЩЬЮ ГЕНЕТИЧЕСКОЙ ИНЖЕНЕРИИ

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Абстракт

Развитие новых биологических технологий, включая новейшие достижения в области генетической инженерии, поднимая ряд социальных и моральных вопросов, создало также проблемы в области интеллектуальной собственности.

В рамках статьи автор, обсуждая особенности генетической инженерии с правовой, этической и философской точки зрения, представил содержание последней и ее связь с правом, а также возможные последствия экспериментов в данной области, одновременно раскрывая содержание патентирования генов. В работе более подробно обсуждены проблемы патентирования живых организмов и человеческих генов.

В результате проведенного исследования автор изложил свою позицию относительно возможности патентирования генов, в том числе модифицированных с помощью генетической инженерии, живых организмов, а также человеческих генов и возникающих над ними возможных прав и круга их правообладателей, обозначая возможную сферу правового регулирования данной отрасли.

Ключевые слова – *генетическая инженерия; интеллектуальная собственность; патент на изобретение; патентирование гена; ген, модифицированный с помощью генетической инженерии; патентоспособность; патентирование живого организма; патентирование человеческих генов.*