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Research Article

PHILOSOPHICAL AND LEGAL FOUNDATIONS OF THE METHODOLOGY OF SCIENTIFIC KNOWLEDGE OF THE GENOME

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One of the priority tasks of modern science is the knowledge of the genome in general and the human genome in particular. The human genome as an object of scientific knowledge is also of interest for jurisprudence. The main tasks of legal science in this area are a proactive response to the challenges arising from the development of technologies in the sphere of genetics, constant interaction with other humanitarian, natural and technical sciences and the development of interdisciplinarity of scientific knowledge about the human genome. Purpose of the study is to formulate the philosophical and legal foundations of interdisciplinary scientific knowledge of the genome. Tasks are development of a system of methods for interdisciplinary genome cognition; formation of a conceptual list of categories 'genomic information'; search for the criterion of truth in interdisciplinary knowledge of the human genome; formulation of the main prospects for the development of the 'bio-law' branch, its civil and criminal law aspects. When preparing the work, the empirical methods, the formal legal method, the method of constructing conceptual lists were used. Coherence is used as a truth criterion. The system of methods applicable to interdisciplinary knowledge of the human genome was determined, a conceptual list of the category of 'genomic information' was formed, a coherent criterion of true scientific knowledge was determined as a result of the study. A 'bio-law' branch is being formed as a result of interdisciplinary knowledge. It is assumed that the branch will be functional in

nature; it will combine diverse knowledge (constitutional, civil, criminal, administrative), but the functional unity of the elements of legal impact will be the basis for such unification.

Keywords: *human genome, genomic information, interdisciplinary research, research methodology, bioethics, genetic research*

Introduction

Scientific knowledge of the human genome is one of the priority tasks facing modern science. Legal sciences are no exception, their task is to promptly and responsively respond to new trends, directions and subjects of scientific knowledge, 'come into contact' with other sciences, thereby, developing the interdisciplinarity of scientific research. A wide range of issues related to a new object of legal influence – the human genome – were considered in the previously published works of the research team. Directions of legal impact in the sphere of genomic research; scientific and technological, legal and ethical problems of the study of the human genome; genomic legal relations, their subject, structure and functions; legal mode of the genome were studied and considered. The study was conducted regarding the legal impact on genomic relations in public and private branches of law as well as the study of the genome in the focus of judicial practice.

Trends and forecasts of the development of legal impact on such an object as the 'human genome', related scientific research and its practical use within the legal system were formulated according to the results of the study.

This study transfers to the next level of knowledge, from theoretical to philosophy and methodology of interdisciplinary scientific knowledge of the genome.

Purpose of the study: to formulate the philosophical and legal foundations of interdisciplinary scientific knowledge of the genome.

Tasks: development of a system of methods for interdisciplinary genome cognition; formation of a conceptual list of the category 'genomic information'; search for the criterion of truth in interdisciplinary knowledge of the human genome; formulation of the main prospects for the development of the 'bio-law' branch, its civil law and criminal law aspects.

Hypothesis: the 'human genome' as an object of research is a complex and versatile conception, therefore, the key aspect in the scientific knowledge of the human genome is the application of interdisciplinary methodology of legal, natural and technical sciences.

Materials and Methods

Empiricism in law and empiricism in modern cognition of the genome

The empirical-analytical approach should be considered dominant in terms of organizing target contexts of cognitive activity in the legal science. It is generally accepted that law in its positive expression is the subject of study in jurisprudence, as well as the forms of existence of law in jurisdictional decisions. Hence the main methodological emphasis in legal research follows, which is the technical and legal development of positive law, comparison of positive legal forms in order to find logical contradictions in them (S. S. Alekseev, G. F. Shershenevich).

It is important to understand that the empirical basis of research cannot be reduced to only the subject's sensory perceptions or simple linguistic forms when studying the genome. Empiricism is understood as a sensory reflection of phenomena in unity with logical content, expressed in a certain approach to the subject of cognition. There is always some kind of linguistic expression obtained in the scientific experience of sensory reflection of the studied reality in accordance with this logic. Expressing the results of sensory perceptions in the language of science, the experimentalist inevitably introduces his rational content into the experimental material obtained. In this sense, the concept of 'pure experience' is not acceptable, at least in the study of the genome.

The 'mechanism' of genome cognition is such that the experimental scientist first receives primary scientific knowledge based on experimental data and then forms the corresponding concepts.

The means of empirical work include the formulation of scientific experience (observation and experiment), everyday knowledge (sensory and logical) necessary for a researcher to describe sensory

perceptions arising in the process of observation and experiment, as well as basic fundamental (initial) scientific knowledge necessary for a researcher to setting up the experiment. Finally, the means of empirical work should include the formalization (in some cases – schematization) of their sensory perceptions obtained in experimental research.

As a result of the use of all these means, a primary, relatively simple form of empirical knowledge arises in the form of experience data that capture the real sensory perceptions of the researcher, expressed in the corresponding concepts. A genetic scientist, receiving experimental data, studying them, tries to identify connections and dependencies between them, generalizing them, establishes mathematical and logical correlations, gives them classification. In this case, inductive methods of cognition are used. Mathematical processing is accompanied by various forms of schematization, when the researcher compiles tables, graphs and etc. Everything is subordinated to the goal of establishing and obtaining new scientific data through the establishment of functional dependencies of the obtained quantitative data.

Empiricism in jurisprudence shows the methodological consistency if legal research is focused on the development of questions of positive law. At the same time, an exclusively empirical organization of scientific research of law is impossible insofar as any science operates with a system of ideal objects in their conceptual expression. As a result, the science of law focuses on the development of conceptually-organized knowledge, the development of a theory of the phenomenon, which may be different from its positive-legal construction (M. M. Agarkov).

It is justified to believe that empiricism is the leading, but not the only research base in modern scientific knowledge of law. With regard to the development of a system, the object of which is represented by relations regarding the use of the human genome, the following should be especially noted:

1. Genetics and genomic research operates, first of all, with an ideal sphere, which distinguishes them from traditional experimental natural science (it is sufficient to mention that the well-known spiral structure of the DNA molecule is in fact a theoretical model and its true structure is still unknown).

2. Empirical principles in the theoretical and legal conceptualization of genetic phenomena as socio-legal phenomena are expressed in the exponential development of genomic research, the actual inclusion of the genome (genetic information) in civil circulation.

3. The need for an experiment arises in the course of cognition of the genome. This is a complicated observation. An experiment is a form of scientific experience associated with systematic observations of an object, its individual sides and connections with other objects, which are revealed in the process of artificially created conditions and are also accompanied by test effects of the observer on the object under study. An experiment is always an observation that presupposes a physical connection between an object and an observer, who uses special means of influencing the state of the object; it allows revealing its hidden properties and connections. Such an intervention is aimed at a reliable penetration into the essence of the observed phenomenon. In this case, the preliminary assumptions of the researcher may not be reliable. That is why the initial hypothesis is subject to correction in the course of repeated experiments. Law, in turn, acts as a restraint for any experiments that could damage the anthropological essence of a person. Together with ethics and morality, religious institutions, the law establishes a 'red line' which should not be crossed in any case by researchers of the genome in their cognitive excess.

4. Any property, which is appropriate to an empirical object, can be found in the objects corresponding to it (but not vice versa, since the object does not represent everything, but only some features of the object, abstracted from reality in accordance with the tasks of cognition and practice).

Methodology of interdisciplinary cognition, methodology of interdisciplinary cognition of the human genome, its significance in modern conditions

The interdisciplinarity of research activity is mediated by the key epistemological attitudes of the scientific rationality of the postnonclassical type (V. S. Stepin). Methodological prerequisites for interdisciplinary research are traditionally considered as the following: the unity of the object of science (the objective world – for the natural, the subjective world – for the socio-humanitarian), the similarity of the initial conceptual schemes describing the object (for example, the similarity in the content of the concepts of the state in political science and jurisprudence), as well as the formation of meta-scientific areas of knowledge (systems approach, general theory of activity).

At the same time, the methodology of interdisciplinary cognition in the modern era is characterized by a number of specific features.

Firstly, the basis of interdisciplinary research is not the unity of the object, but the unity of an activity. Hence, the phenomenon that is part of the object of study of natural science (for example, genetic information), being involved in social and legal relations (for example, relations for the protection of human genetic dignity), begins displaying legally significant properties (becomes objects of law, etc.), which predetermines the existence of grounds for interdisciplinary research.

Secondly, the conceptualization of the phenomenon is based on the principle of unity, not the differentiation of sciences, due to which the interpenetration of the initial conceptual schemes (at the level of the methodological approach) sets the boundaries for the emergence of related areas of knowledge (for example, the law-genomic theory).

Thirdly, the formation of related areas of knowledge is carried out in the conditions of Anderssein method, that is, in the context of the possibility of a particular theory in its initial foundations to act as a mean of cognizing an object. Thus, if in the traditional branches of legal sciences the totality of research tools is understandable, then in new branches of legal knowledge that are intensively forming on the basis of law-genomic research, the role of new cognitive means becomes especially important. And here it is very important to analyze the significance of general scientific means, to which, of course, general scientific concepts also belong, regardless of whether they are well-established or still have the status of emerging now.

In this regard, we emphasize that the emergence of new objects and the formation on this basis of subjects of legal science research occur on the basis of a progressive understanding of the unknown properties of the phenomenon. The epistemological continuation of this fact should be the emergence of new concepts, since they can serve as the basis for private concepts and even theories. Thus, the general scientific concept of 'genomic information' in a natural way and realizes this role in legal genomic research.

In our opinion, 'genomic information' represented by a conceptual list decomposed into species terms (types of genomic information, access mode to genomic information, biological sample of genomic information, method of obtaining genomic information) can serve as the basis for building a new interdisciplinary law-genomic theory, since the theorization of any science is connected with general scientific concepts and conceptual lists of mutual conditioning in the epistemological process. For example, the very appearance of the general scientific concept of 'genomic information' in the thesaurus of legal science is a rather vivid evidence of the developing theorization of legal knowledge. Accordingly, the formation of the general scientific concept of 'genomic information' is a statement of a high level of abstraction of legal theory and significantly affects the subsequent intensification of this process.

The problem of truth in interdisciplinary cognition of the human genome

Traditionally, two large groups of truths are distinguished in the philosophy of science: empirical and non-empirical. The first one includes Aristotle's correspondence theory of truth (correspondence of knowledge to objective nature), as well as other theories (experimental testability, semantic consistency); the second includes coherent, conventional and other theories.

It is generally accepted that the task of philosophy is to develop an understanding of truth, and specific sciences develop its criteria in their methodologies (E. M. Chudinov).

Interdisciplinary cognition, in this sense, constructs its subject on the basis of the methodological synthesis of conceptual ('knowledge') schemes (G. P. Shchedrovitsky, V. N. Sadovsky); hence, the subject of interdisciplinary research is set by the initial philosophical, meta-scientific and specific scientific attitudes, being formed as a conceptual (theoretical) model. In this sense, the methodological capabilities of classical philosophical positivism are limited, and, therefore, the criterion of experimental verification is not applicable in interdisciplinary research in all cases.

The aspect of truth criterion in the methodology of scientific knowledge is inextricably linked with the understanding of the subject of science, the source of scientific knowledge and the specifics of its types. Following traditional approaches, practice as a criterion of the truth of scientific knowledge can be considered in three aspects: 1) verification of scientific theoretical positions in the experiment; 2) the introduction of scientific discoveries (both empirical and theoretical) into production; 3) verification of any provisions of science (including the most general ones) in all common human practice for a long time.

The first of these criteria is most often applied in scientific knowledge of the genome. However, all human practice should be recognized as the ultimate criterion of truth.

Additional non-empirical criteria for scientific truth include intuitive conviction, i.e. reliability related to our trust in experience data, logical evidence based on the reliability of logic and mathematical calculations. The subjective experience of the researcher cannot be disregarded in conducting scientific research.

Each of the non-empirical criteria of truth itself needs a criterion of practice. Intuitive conviction must be tested first by theoretical analysis and then by repeated experiments. Logical evidence acquires value if the initial statements are proven.

A key role in interdisciplinary research is played by its methodological organization, its initial scientific and cognitive strategy. Hence, the truth of interdisciplinary knowledge (in conditions when its content cannot be unambiguously correlated with a specific empirically valid object) is determined by the consistency of its methodological foundations. In this sense, the main criterion for an interdisciplinary approach is coherence, not reference (as in classical science).

Results

Empiricism in law and empiricism in modern knowledge of the genome is not the only method of scientific knowledge. It is the primary form of obtaining scientific knowledge based on experimental data.

The appearance of the general scientific concept of 'genomic information' in the thesaurus of legal science makes it possible to form and expand the corresponding conceptual list:

The truth of interdisciplinary knowledge (in conditions where its content cannot be unambiguously correlated with a specific empirically valid object) is determined by the consistency of its methodological grounds. In this sense, the main criterion of an interdisciplinary approach is coherence, not reference (as in classical science).

Discussion

Prospects for the formation and development of the 'Bio law' branch

Now biology and medicine are being actively developed, they are often discovering new and not always friendly technologies in relation to the very nature of man and his rights. Biomedical challenges form a new way of life (Romanovskiy & Romanovskaya, 2018) based on ethical, moral, bioethical norms and, as a result, new approaches to legal impact on these processes are being formed.

The idea of the emergence of a new generation of human rights and the laying of this new type of rights as the basis for the formation of a biological law, biomedical law has repeatedly become the subject of a scientific dispute between modern scientists, on the one hand, paying attention not only to the extensive, but also to the intensive development of new legal relations, as well as the need for prognostic regulation, and on the other hand, expressing doubts about the formation of new legal contours of the international vocation of the fourth and fifth generation of human rights (Nikitina, 2020).

Despite the current discussion, at the present time it is possible to definitely distinguish a group of human rights, which are based on a fundamental belief in the human right to independently dispose of his body: to carry out 'restoration' or change the functional characteristics of the body. These rights, as purely personal, received different legal establishment: as somatic and as human rights in the field of bioethics.

The theoretical development of somatic rights was carried out within the framework of constitutional law (V. I. Kruss, M. A. Lavrik) and the theory of law (A. I. Kovler, O. E. Starovoitova). This category is found as 'protection of rights and freedoms in the field of bioethics' in international law (Valeeva, 2011). According to the founder of the theory of somatic rights V. I. Kruss, the nature of somatic rights is extremely peculiar: here a person not only claims to change bodily integrity, but also puts forward certain claims to society. The subject of legal claims is also peculiar: being only partly material, it is at the same time fundamentally determined by the personal characteristics of the possessor of the right (Kruss, 2000).

The problem of defining human rights within the structure of bioethics is also uncertain in connection with the relatively recent origin of the very term 'bioethics', introduced by the American oncologist W. R. Potter. Bioethics is generally defined as a culture of limits, aimed at building interaction between

fundamental principles and human views and the evolving biomedical field in order to protect the human personality and dignity (Kayumova, 2019). The peculiarities of the bioethical approach are its interdisciplinarity, pluralism and publicity. Thanks to the latter bioethics becomes a factor in the formation of public space and an important form of manifestation of the position of civil society. And in this aspect, according to P. D. Tishchenko, bioethics can be considered as a source of development of law when, in the course of bioethical discussions, a new subject of legal influence is formed, or when bioethics acts as a subsidiary mechanism of social control (self-control of an individual and social groups) in relation to the law, or, finally, when bioethics is used as a 'soft power', supplementing the government machinery of coercion with a special deliberative mechanism for the formation of collective will (Trikoz, 2019). And in this case, bioethics becomes the main source of the formation of both bio-politics and bio-law.

The very term 'bio-law' has a conventional meaning. We are talking, in this case, about the formation of a system of legal norms, the subject of which are relations regarding the manifestation of biologically significant human properties (first of all, genetic dignity, biological material, etc.) as socially significant components of reality.

The idea of human dignity as a fundamental concept of natural human rights is revealed in a new way in the area of biomedical technologies. The concept of genetic dignity, introduced over a quarter of a century ago by M. I. Kovalev, as a specific object of legal protection (Sergeev & Kozyrin, 2019), which is a human genetic code that excludes the possibility of accidental or malicious external negative impact that destroys the genetic identification of its bearer (Kozachenko & Sergeev, 2021), is currently associated with the modern transformation of the category of human dignity as a whole in the new biotechnological era of mankind. The modern concept of dignity, according to some scientists, has significant connections with modern biological ideas about people, which can be said about the 'biological matrix of dignity' (Kravets, 2020). The authors, noting the polymorphic nature of human dignity, note that it penetrates into all areas of modern medicine and bioethics, when they discuss complex issues of legal, existential and moral legitimacy of the use of somatic rights in terms of disposing of their bodily capabilities. However, the concept of dignity alone cannot solve most of the dilemmas associated with biomedical practice. This is why international bio-law brings together, on the one hand, an appeal to human dignity as an overarching principle, and on the other hand, an appeal to human rights, which can provide an effective and practical way to solve bioethical problems at the global level (Kravets, 2019).

It is assumed that the branch of 'biological law' will be functional in nature (L. N. Berg) in the sense that it will combine diverse knowledge (constitutional, civil, criminal, administrative), but at the same time the basis for such associations will be the functional unity of the elements of legal impact, which manifests itself in a holistic conceptualization of the biological essence of a person by legal means.

For example, considering a genomic legal relationship as a real, factual, social relationship that has arisen in a specific life situation, associated with the use (research, application, storage) of a gene and (or) a gene sequence (genome), which has acquired a legal form as a result of the envisaging of this life case by the rule of law of the current law, agreement, judicial (administrative) act, it should be understood that legal relations of this kind are always complex, in connection with which it is required to develop a single conceptual apparatus for them, universal, as far as possible, for constitutional, civil, criminal, administrative law.

The civilized aspect of the 'bio-law'

Having stated the inter-branch nature of the phenomenon under study, it should be noted that it seems possible to use preferentially civil law tools in order to determine the objects, structure and content of genomic legal relations and some principles of 'biological law'.

So, the genomic legal relationship is quite conceivable within the framework of the following civil law institutions with their specific legal regimes:

intellectual rights to the results of intellectual activity (to create new genes, genetic constructs, their modifications, etc.),

purchase and sale or alienation on other grounds of genetic (biological) material,

providing services for the impact on the genome or its research, including for medical purposes,

research and development work related to the genome,

tort liabilities from inflicting harm (human health, genetic wealth and environmental well-being, etc.),

safeguard and protection of the rights and legitimate interests of citizens as consumers (in particular, consumers of genetically modified food and not only).

Speaking about the object of a genomic legal relationship as a blessing, to which this legal relationship is directed and has a certain impact, from the point of view of civil law, three main benefits can be distinguished, namely:

- 1) information,
- 2) biological materials,
- 3) services and the results of work.

Genomic legal relationships are diverse, and in connection with this diversity, their objects can also be very different: often a genomic legal relationship arises from an essentially civil contract, and when decoding the genome of a particular person (for example, when carrying out molecular monitoring in order to diagnose a disease for its early stage), carried out by a special organization on the basis of an appropriate agreement with a patient, the object of a genomic legal relationship will be, among other things, the services of such an organization.

Manipulations with genetic material today are mainly subject to special norms that are not always civilized in nature, however, with the expansion of the scope of application of the relevant technologies, their transcendence from the purely medical sphere and widespread penetration into the service sector (for example, for cosmetic purposes) and other areas of human activity is quite predictable. In addition, one should not forget about the existence of such a direction of genetic application and genomic technologies as agriculture: in this industry, the achievements of genetics and genomics have long been used, including for the provision of services and work, outside the 'medical' context.

It should be noted, however, that the main benefit is information for which a genomic legal relationship arises. The genome is a complex phenomenon that includes elements of matter, information and energy; however, from the point of view of civil law, its information component is prevalent. While avoiding a mechanical analogy with a computer program, it is worth paying attention to the high degree of similarity. So, the nucleotide bases of our DNA, in a way, are elements of the program code by means of which the characteristics of our biological species and each of us individually are set. The composition, structure, sequence of synthesis of certain components, metabolism – all this is 'written down', and, therefore, can be read and in some cases even edited. The knowledge of what exactly this or that combination of nucleotide bases (gene) encodes, located on a particular piece of DNA, is definitely a good in understanding the good as an object of legal relationship. Information about the location of genes in the genome, about their sequence is also of great value: it is this knowledge that allows genomic manipulations, 'cutting' or 'inserting' the necessary genes and thereby modifying, editing the genome.

Every living creature, not excluding man, is the result of internal biological construction. Very conditionally, due to the incomparable complexity of the processes, and very carefully (due to their heterogeneity), one can draw an analogy between the technologies of bio-printing that already exist today, when computer information as a set of coding symbols is embodied in a biological object (organ, cartilage, elements of blood vessels, etc.) and the development of a living organism (including a human), during which hereditary information is realized in the material world – also as a kind of program. Biological samples (materials) containing this program in tangible form do not always refer to objects of civil rights, but in any case have value as:

- 1) sources of scientific data (material for research),
- 2) sources of data about a specific information carrier (subject or object, if we are not talking about a person).

Thus, as a blessing that is an object of a genomic legal relationship, the value of biological material is secondary: such material is important not in itself (unlike, say, donor organs and tissues - the situation here is similar only externally), but as a repository of information. Accordingly, from a civilized point of view, it is information that appears to be the main (but, of course, not the only) object of the future 'biological law'.

It is hardly realistic to reduce the legal regime of information to the framework of one industry (for example, genomic information, considered as personal data or as information constituting a state secret, has a different, completely specific legal regime), however, to a large extent, the norms of civil law are applicable to information (of course, taking into account the constitutional provisions) and the corresponding

legal instruments. In this case, it is necessary to conceptually determine whether to consider genomic information as:

- text (code), by analogy with computer programs, with the extension of copyright rules to it,
- technical solution (subject to patent law),
- other information with limited access, in respect of which a special regime should be established, similar to the regime of personal, family or commercial secrets.

There are pros and cons for each of these approaches.

In particular, the assessment of genomic information as a code (text) is interesting due to the easily traceable external functional analogy (including with computer programs, also protected as text) and the possibility of obtaining legal protection without the need to comply with any formalities (in any case, in the states parties to the Berne Convention for the Protection of Literary and Artistic Works of September 09, 1886). The main problem in this case is the matter of authorship: it is unlikely that it can be recognized for anyone in relation to the source code (if we continue the analogy with a computer program, then also the object code, if it is of natural origin). Science is still only moving towards the creation of truly author's genes. However, when this is implemented, perhaps, copyright has a chance to be the most convenient civil law tool in the sphere of genomics (it is speculatively possible to assume even the appearance of corresponding works of art in the future).

The proposal to use the norms and methods of the patent law for genomic legal relations is also very controversial, both in science and in practice (*Association for Molecular Pathology v. Myriad Genetics, Inc.*). Thus, the arguments 'against' are the lack of novelty as a criterion of patentability in individual genes and natural genomes (V. P. Kamyshevskii, A. I. Stanishvskii) as well as novelty and inventive level in the knowledge of the location of a particular gene or their sequence (previously issued US patents of this kind were canceled as soon as the US Supreme Court understood the essence of the matter and realized that such patents gave the right to prohibit others from reproducing part of human DNA to others - if approach it approached formally, then reproduction is natural). At the same time, the patentability of technical solutions is recognized, with the help of which it became possible to extract and purify genes, modified or artificial DNA or DNA sections. Modern Russian patent legislation operates with the concept of 'genetic construction' to denote a patentable object, considering such structures as technical solutions related to the device - a kind of analogue of engineering structures, only instead of parts and blocks connected by soldering, welding, etc. disclosure of the invention indicates such specific structural elements as an enhancer, promoter, terminator, initiation codon unit, linker, foreign gene fragment, marker, flanking regions and methods for building the desired constructs using these elements. Those elements of the genome that have been modified and the properties that the corresponding object should acquire as a result of such modification are indicated for genomic constructs and the results of their application (such as transformed cells, transgenic plants and animals).

Thus, the main argument 'for' the application of patent law is that genomic and genetic objects are already being patented (very actively in a number of countries). This, however, does not prevent many prominent scientists from being opposed to patenting - in their opinion, patenting scientific results in the field of genetics and genomics hinders the development of science and hinders the application of its achievements for the benefit of humanity (see 'Who Owns Science? The Manchester Manifesto').

The point of view on the need for legislative recognition of the genome as a separate independent object of civil rights, which has a specific complex legal regime, is also valid. It is possible that in the future such an object of civil rights as the 'genome of the organism' will appear in the legislation along with the protected results of intellectual activity and the means of individualization equated to them. The advantage of this solution is the ability to fully take into account the nature and complexity of the object, its features, the minus is the creation of a new entity with the existing, in general, the ability to get by with the existing legal means (as happened in the case of computer programs, considered by copyright as literary works).

In addition, the problem of collection, storage, use and protection of large arrays of genetic and genomic data deserves special attention. In conditions when the amount of data of this kind, collected and stored in the world, begins to be estimated in exabytes, the quantity turns into a new quality that was not previously inherent in the object: genetic information on specific people (and not only people), materials for decoding specific genomes, other data processed and structured with the help of modern technologies become 'big data' - a completely specific information object that requires a separate legal understanding. Traditional

civil law constructions of copyright and related rights of the manufacturer of the database do not fully meet the needs caused by the emergence of 'big data', as well as the current legislation on the protection of information, including personal data (A. I. Savelyev).

In any case, at present, the decision on the extent to which a gene, genome, their modifications, arrays of genetic information derived from these arrays (for example, medical risk profiles) can be considered as objects of absolute rights and objects of civil turnover, which should their legal regime be, the form and procedure for making transactions with them, is one of the pressing problems that needs careful scientific discussion and legislative study.

Criminal law aspect of 'bio-law'

The rapid development of biomedical technologies observed today and the associated predictive results in the sphere of genome and genomic information, considered so far from the perspective of futurological ideas and meanwhile significantly deviating a person from the trajectories set by wild nature, against the background of the need for effective protection of basic individual rights, including rights to life and health protection, the right to respect for the human dignity of the individual and private life, require the development of effective mechanisms of criminal law protection, both of existing objects of protection, and, taking into account the preventive role of criminal law, giving this status to other potentially possible objects in order to prevent possible violations in this area. And from these points of view, the similarity of the biological law and criminal law problems is obvious in ensuring the protection of fundamental human rights and freedoms and the protection of universal values. Thus, the shift in emphasis within the boundaries of knowledge of life, as a result of which the individual himself becomes not only an object of rational knowledge, but also his work of art, gives rise not only to new problems and issues in the development of an effective mechanism for the criminal law protection of a person's life and distinguishing the moments of the beginning of life and its criminal law protection, but also require a critical rethinking of the existing legal approach to objects and subjects of criminal law protection, including the development of a special legal regime for the criminal law protection of human embryos, as well as revision of the criteria for their criminalization and penalization.

At the same time, the subsidiarity of the nature of criminal law, the prescriptions of which outline the boundaries of lawful and illegal behavior, the content of which is established by regulatory branches, predetermines the appeal to diversified knowledge. Thus, the criteria used today for the emergence of human life as an object of criminal law protection directly depend on advances in the sphere of medicine.

Accordingly, 'the delay in changing protective norms can create complex legal collisions that actually paralyze the law enforcement mechanism' (Z. A. Neznamova).

Genetic information also belongs to the number of objects of criminal law protection requiring the actualization of scientific interest. Having acquired the status of the main resource for the development of modern society, no less significant than material, raw materials, financial, etc., information has a tendency to inevitably increase, including due to the emergence of new knowledge. Not so long ago, genomic research was one of the unique, and today, turning to them in transplantation, diagnosis and treatment of certain types of diseases in reproductive medicine, personality identification, etc. has become a daily practice, and these processes will only grow.

Accordingly, genomic information bases in the near future will find their large-scale implementation, acting as another resource that combines both undoubtedly positive and destructive potential. And since the prognostic potential of genomic information is uncertain, then the progress in this area is perceived by society, rather, with growing concern due to the scale of possible threats up to the creation of biological genetic weapons.

The value and interest of genomic information generated by it, which can influence the fate of several generations, for a wide variety of subjects (employers, insurance and credit organizations, specialists in the creation of weapons, etc.), as well as the form of its existence, which is impossible without the use of information networks, computer technologies, communications and telecommunications, which in itself causes vulnerabilities in its protection, including due to the potential criminality of the virtual space itself, which has a low level of transparency and, conversely, a high level of anonymity, significant obstacles in identifying a virtual network user, exposing and counteracting its criminal activity, require the creation of effective mechanisms to protect the developed genomic databases, including by improving the legal system.

However, prevention of the noted and other possible threats should be systematic. It is necessary to influence both the very environment of existence of genomic information, increasing the level of its

disadvantage (for example, by increasing the identification requirements for working on the Internet, eliminating its anonymity, registering means of communication in cyberspace, etc.), and on its users (by increasing the level of their information culture and victimologic prevention).

In addition, it should be borne in mind that since the human genome, as a set of hereditary material enclosed in a cell, contains information related to his genetic relatives, respectively, the dissemination of such information may be undesirable for a whole circle of people or directly pose a threat to their rights or legitimate interests of many persons, then simply giving genomic information the status of personified legal protection seems to be insufficient.

In turn, giving a special status to genomic information also requires a change in approaches to its processing, including the establishment of a limited range of circumstances in which actions with genomic data are permissible with the consent of a specific subject of personal data. Protection of genomic information from unauthorized access to it, its use, disclosure, distortion, alteration, systematization or blocking should be carried out at the state level – under the control of the relevant state bodies.

Conclusion

Among the fundamental concepts of biological and legal research (formed mainly by external means), one should include the concepts of the genome as an object of law, the genetic dignity of a person, his somatic rights (in particular, the right to his own genetic material), and biological material. Moreover, these concepts should be based on the corresponding conceptual developments from the relevant areas of knowledge and, at the same time, be legal, that is, describe these phenomena as legal regimes, in the traditional conceptual scheme of jurisprudence.

It should be noted that the initial hypothesis of biological and legal research is the assumption that traditionally invariant jurisprudence (biological, somatic, genetic, etc. components of a person) is capable of influencing legal reality (at least based on anthropological contexts (O. A. Puchkov). Hence, it will potentially require a rethinking of the basic concepts of jurisprudence (object of law, legal regime, etc.).

The issue of the principles of biological and legal research and the principles of 'biological law' has not yet been worked out. It seems that along with the currently emerging concept of 'digital human rights' (for example, the right to anonymity in the information environment), the concept of biological human rights will also be formed, which will be based on specific principles (in particular, respect for the genetic dignity of a person, protection of his somatic rights, inadmissibility of arbitrary correction of the genome and cloning of a person, etc.).

References

Kayumova, A. R. (2019) Human Rights Protection in the View of Application of Modern Biotechnologies: Some Issues. *Jurist.* (1), 64–71. (in Russian).

Kozachenko, I. Ya. & Sergeev, D. N. (2021) *Geneticheskie issledovaniya: zakonodatel'stvo i ugolovnaya politika* [Genetic research: legislation and criminal policy]. Moscow, Prospect. (in Russian).

Kravets, I. A. (2019) The Constitution of the Russian Federation, Human Rights and Human Dignity: Dialogue of Constitutional Theory, Practice of Constitutional Justice and International Norms. *Juridical Science and Practice.* 15(2), 93–104. <https://doi.org/10.25205/2542-0410-2019-15-2-93-104>. (in Russian).

Kravets, I. A. (2020) Dignitatis humanae, sovremennyyi konstitutsionalizm i pravovaya ekzistentsiya: filosofsko-antropologicheskie, konstitutsionnye, mezhdunarodno-pravovye i sotsial'no-politicheskie aspekty [Dignitatis humanae, Modern Constitutionalism and Legal Existence: Philosophical-anthropological, Constitutional, International Legal and Socio-political Aspects]. *Obshchestvennye nauki i sovremennost'*. (5), 38–52. <https://doi.org/10.31857/S086904990013046-2>. (in Russian).

Kruss, V. I. (2000) Lichnostnye (somatic) prava cheloveka v konstitutsionnom i filosofsko-pravovom izmerenii: k postanovke problem [Human rights (somatic) in the constitutional and philosophical-legal dimension: towards the problem]. *State and Law.* (10), 43–50. (in Russian).

Nikitina, E. E. (2020) Sistema prav i svobod cheloveka v usloviyakh tekhnologicheskoi revolyutsii [System of Human Rights and Freedoms in the Context of the Technological Revolution]. *Journal of Russian Law.* (8), 27–44. (in Russian).

Romanovskiy, G. B. & Romanovskaya, O. A. (2018) *Prava cheloveka, genetika i sovremennaya biokriminologiya* [Human Rights, Genetics and Modern Biocriminology]. *State and Law*. (3), 64–71. (in Russian).

Sergeev, D. N. & Kozyrin, A. A. (2019) *Geneticheskie issledovaniya. Redaktirovanie genoma. Grani ugolovno-pravovogo regulirovaniya* [Genetic Research. Genome Editing. Facets of Criminal Law Regulation]. *Eurasian Law Journal*. (5), 253–256. (in Russian).

Trikoz, E. N. (2019) Protection of Human Rights in the Context of the Development of Bioethics and Genomics (Thematic Review of the International Round Table. *RUDN Journal of Law*. 23(1), 141–154. <https://doi.org/10.22363/2313-2337-2019-23-1-141-154>. (in Russian).

Valeeva, R. M. (2011) *Mezhdunarodnaya i vnutrigosudarstvennaya zashchita prav cheloveka* [International and Domestic Protection of Human Rights]. Moscow, Statut. (in Russian).

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