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Imperative and Dispositive Norms in Legal Regulation of Genetic Research in Russia

Normas imperativas y dispositivas en la regulación legal de la investigación genética en Rusia

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ABSTRACT:

The article is devoted to the analysis of diverse utilization varieties of regulatory framework at adjusting genetic techniques and global legal practice research. Internal determinants of the development of national systems and external universal laws of legal transformation influence the evolution of views of the professional community of lawyers in Russia and in foreign countries, regarding the choice of dispositive or mandatory ways of regulating genetic research. The discussion on a number of legal institutions and on the choice of effective methods and forms of legal regulation in the world and Russian legal practice continues.

KEYWORDS: Dispositive norms, foreign, genetic, imperative norms, law..

RESUMEN:

El artículo está dedicado al análisis de diversas variedades de utilización del marco regulatorio para ajustar las técnicas genéticas y la investigación de la práctica legal global. Los determinantes internos del desarrollo de los sistemas nacionales y las leyes universales externas de transformación legal influyen en la evolución de los puntos de vista de la comunidad profesional de abogados en Rusia y en países extranjeros, con respecto a la elección de formas obligatorias o dispositivas para regular la investigación genética. Continúa el debate sobre una serie de instituciones jurídicas y sobre la elección de métodos y formas eficaces de regulación jurídica en el mundo y la práctica jurídica rusa.

PALABRAS CLAVE: Extranjero, genética, ley, normas dispositivas, normas imperativas..

INTRODUCTION

To some extent, this paper is a continuation of the research commenced in the article entitled “The Rosie Effect” or the Dialectics of the Social and the Biological in the Evolution of the Legal Map of the World in the 21st Century” (Zakharova: 2020, pp.50-56). In the aforementioned article, the author metaphorically refers to Graeme Simsion’s book *The Rosie Effect* which very vividly describes the futile attempts of the protagonist, professor of genetics, to find a life partner based solely on genetic compatibility of the representatives of different sexes. His search comes to a happy ending in the person of a girl named Rosie only when he “turns

over the card” with the genetic mantra and begins to see the aspects of social practices in the chemistry between the two sexes. Thus, the novel’s happy end lies in the sphere of the dialectical unity of the social and the biological in terms of solving the problem of choice through the Hegelian law of the unity and struggle of opposites (Fagot-Largeault:1985; Reich: 1995; Laurie: 2011;Bledsoe: 2017, pp.142-147; Langhof et al.: 2019, pp.176-185).

It is equally important, however, not only to present the dialectics of the two related determinants mentioned above, but also to see what key mechanisms of legal regulation are used by legislators in the sphere of genetic research in different countries of the world (Dierickx&Borry: 2009; Parodi: 2015; Boggio:2017, pp.102-120; Hainaut et al.: 2017; Savatt et al.: 2019, pp.153-161). Below we describe a palette of dispositive [discretionary] and imperative [peremptory] regulation in this sphere.

METHODOLOGY

Both general and special methods of cognition were used in course of work on this paper. The work was based on a comparative legal method realized within the framework of interdisciplinary (comparison of the legal doctrine with the related spheres of knowledge, such as philosophy and sociology), cross-branch (comparative analysis of the approaches used in comparative law, in philosophy and theory of law as well as in branch legal disciplines), cross-border (comparison of different national legal systems with each other and with international law provisions) as well as chronological (historical comparative analysis) approaches. The authors relied on the principle of methodological pluralism in their research, which allowed them to look at the problem under examination from various points of view, thus ensuring a comprehensive nature of cognition.

RESULTS

According to the legal doctrine that has developed in the general theory of law, imperative [peremptory] norms strictly determine the rights and obligations of the subjects of law, without allowing them any freedom of discretion. Dispositive [discretionary] norms (derived from the Latin term *dispositivus* meaning disposing, discretionary) are valid when the parties have not established their rights and obligations through an agreement, allowing the subjects of law the freedom to choose how to act.

The choice between the imperative [peremptory] and the dispositive [discretionary] option for resolving various matters is largely determined by the peculiarities of the national legal system within which the relevant provisions are established. At the same time, in some instances, we can also observe a largely unanimous opinion of the global legal community with regard to the essence of provisions on certain issues of legal regulation of genetic research. Such, for example, is the imperative [peremptory] norm prohibiting human embryo editing. However, scientific progress in this sphere is unstoppable and some countries are now moving out of the prohibition field with regard to this extremely aleatory issue. For instance, back in 2016, the UK Human Fertilisation and Embryology Authority allowed genetic modification of human embryos. Dr. Kathy Niakan of the Francis Crick Institute is the first person in the world to gain regulatory approval for research involving human DNA editing right inside a fertilized cell. The goal of the researcher is to identify the causes for miscarriages. She wants to understand which genes are needed in the earliest stages of pregnancy for human embryos to develop successfully. Paul Nurse, Katie’s chief and Director of the Francis Crick Institute, said that the research data will increase the success rate of in vitro fertilization (IVF) (Hansson: 2009, pp.8- 12).

In the Russian Federation, the issue of embryo genetic engineering is settled through civil law protection mechanisms. Article 1349 of the Civil Code of the Russian Federation stipulates that the following cannot

be objects of patent rights: 1) human cloning techniques and a human clone; 2) techniques for modifying the genetic integrity of human germline cells; 3) use of human embryos for industrial and commercial purposes; 4) the results of intellectual activity specified in paragraph 1 of this Article, if they contradict public interests or the principles of humanity and morality. Thus, as per the aforementioned Article, the relevant research is not subject to patent protection.

However, the so-called case of Professor Rebrikov (Doctor of Medical Sciences, Professor, Vice-Rector for Research in Pirogov Russian National Research Medical University) makes the situation in the legislative field in question less univocal. We are referring to the fact that Professor Rebrikov presented to the scientific community a unique genetic technology for editing the human CCR5 gene in order to introduce the Delta32 homozygous deletion (in both chromosomes) at an early stage of embryonic development, including production of ribonucleoprotein (RNP) selectively targeting a specific area of the human CCR5 gene, a single-stranded donor DNA, and a protocol for using the listed reagents for human embryo editing. This method could become an effective medical pregnancy planning technology for HIV-positive women with a weak response to antiretroviral therapy. However, Rospatent [the Russian Federal Service for Intellectual Property] refused to issue a patent to Professor Rebrikov on the grounds that the proposed genetic tweak involved actions with germline cells containing a modified genome that includes the main part of the human genome and, therefore, such technology cannot be the object of patent rights in accordance with paragraph 4 Article 1349 of the Civil Code of the Russian Federation. In Professor Rebrikov's opinion, however, these arguments are not justified, since the objects of his research – the zygote and the products of the first divisions thereof (blastomeres) – are not germline cells. So far, Professor Rebrikov has failed to prove his case in court and bring the proposed scientific technology into the legal zone.

In most countries of the world, the group of imperative [peremptory] norms also includes regulations related to biobanking. In the Russian Federation, such regulations are set out in the Requirements for Organization and Operation of Biobanks and Rules for Storing Biological Material, Cells for Cell Line Preparation, Cell Lines Intended for Biomedical Cell Product Production, Biomedical Cell Products (Order of the Ministry of Health of the Russian Federation No. 842n [in Russian: 842Н] dated 20 October 2017 On Approval of the Requirements for Organization and Operation of Biobanks and Rules for Storing Biological Material, Cells for Cell Line Preparation, Cell Lines Intended for Biomedical Cell Product Production, Biomedical Cell Products). The aforementioned document, in particular, stipulates that the head of any entity handling [dealing with] biomedical cell products must ensure approval of documents regulating, without limitation, the procedure for employees' actions when storing biological objects and biomedical cell products in biobanks, the procedure for biobank measuring instruments [meters] and equipment maintenance and checkup, record and report keeping/drawing-up and storage, receipt, transportation and placement of biological objects and biomedical cell products in biobanks. Similar norms are stipulated in the biobanking legislation of other countries (Haga&Beskow: 2008, pp.505-544; Mascalzoni: 2015; Kvit: 2017).

A vivid example of the choice of an To some extent, this paper is a continuation of the research commenced in the article entitled "The Rosie Effect" or the Dialectics of the Social and the Biological in the Evolution of the Legal Map of the World in the 21st Century (Zakharova: 2020, pp.50-56). In the aforementioned article, the author metaphorically refers to Graeme Simsion's book *The Rosie Effect* which very vividly describes the futile attempts of the protagonist, professor of genetics, to find a life partner based solely on genetic compatibility of the representatives of different sexes. His search comes to a happy ending in the person of a girl named Rosie only when he "turns over the card" with the genetic mantra and begins to see the aspects of social practices in the chemistry between the two sexes. Thus, the novel's happy end lies in the sphere of the dialectical unity of the social and the biological in terms of solving the problem of choice through the Hegelian law of the unity and struggle of opposites (Fagot-Largeault: 1985; Reich: 1995; Laurie: 2011; Bledsoe: 2017, pp.142-147; Langhof et al.: 2019, pp.176-185).

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The dispositive [discretionary] norms are most widespread in the so-called private segments of law. However, some instances of dispositive [discretionary] norms can be also seen in the regulation of public legal relations. In this regard, one of the representative vectors for legal regulation of genetic research are the norms related to organization and work of committees on bioethics. Continuing Vladimir Przhilensky's train of thought, it should be noted that one of the functions of such committees is to transfer the issues related to medical ethics from the so-called gray ethical zone to the white ethical zone (Przhilenskiy: 2020, pp.57-68). The organizational core of such committees should be the principle of interdisciplinarity, as pointed out by Gilbert Hottois (Hottois: 2007, pp.35-46).

A new, but very promising in terms of enhancing the efficiency of the legal regulation of genetic research, set of norms are the dispositive [discretionary] norms related to genetic education [awareness-raising with regard to genetic issues].

We have to note that in general the need for narrowly focused education in modern society is rising. Incontemporary realities, the abilities of manipulations targeted for genetic transformation of humans, creation of genetic passports, increasing knowledge about monogenic diseases and the emergence of methods for genetic correction, the opening of opportunities to help people with genetic abnormalities, are requiring for genetic education, including legal knowledge.

The foregoing points out the need of genetic education and its regulation by law. From a general theoretical point of view, it is important to emphasize that both the methodological and content aspects of genetic education are important here.

At the same time, if the methodological side of the issue is quite clear, then the content side needs to be worked out and adapted for educational purposes.

A fairly stable legal reality that reacts with a certain inertia to the challenges of time, "did not have time" to quickly prepare for the regulation of genetic transformations, life in the conditions of the world COVID-19 pandemic, genetic testing processes of various types and genetic education.

In Russia, a unified concept of legal education has not been approved at the federal level, and regional concepts have been adopted in certain regions of the country.

It is also observed in many countries of the world. But the situation is beginning to change quickly. All this leads us to the need to consider legal models for fixing the structures of medical education from a general position – general medical and sanitary education.

Traditionally, there are two main models for fixing and broadcasting the content of genetic education: fixing the basic foundations in policies, usually broadcast through official reports, for example, in the United States, and the adoption of regulations in the field of education.

In light of recent events the experience of France is particularly interesting on 2 December 2011 there was adopted the policy in educational sphere and healthcare in educational centers (Politique#ducative de sante# dans les territoiresacade#miques) which states the mechanism for providing public institutions for medical and sanitary education is outlined and main priorities in this area are named. This policy is a general framework document in the field of health education, in fact, it is a manifestation of intersectoral regulation containing programmatic components. There is no clear designation of genetic education in this document, but certain framework principles of medical education in general are settled. An interesting practice has developed in the field of genomic research and education in the United States of America. In January 2015, Barack Obama announced the launch of the Precision Medicine Initiative, which launched the All of Us project. The purpose of this longitudinal study is to find more effective methods of treatment and prevention of various diseases.

In some instances of legal regulation of genetic research, we see an obviously debatable nature of adequate norm choice in the "dispositive – imperative" dichotomy. Such instances of legal regulation include, in particular, genetic information storage and use.

A multidimensional institution in this regard is the so-called "genetic passport" announced to be created in the Russian Federation, which is essentially a set of genetic (DNA) markers distinguishing a particular person from the other members of society. The initiative is formally based on the Decree of the President of the Russian Federation No. 97 dated 11 March 2019 On the Fundamentals of the National Policy of the Russian Federation in the Sphere of Ensuring Chemical and Biological Security up to 2025 and Beyond.

DISCUSSION

The analysis of the aforementioned initiative logically leads to a series of questions. Should a genetic passport for a citizen of the Russian Federation be considered as an opportunity or as a necessity? Is it a dispositive [discretionary] or an imperative [peremptory] norm? Is it necessary to show this document when applying for a job, etc.? So far there are no definite answers to these questions. However, in any case, technological advances cannot be used to diminish the rights and legitimate interests of the individual.

As international practice shows, more specific aspects of genetic information use are often associated with the application of criminal law norms. Even the rules for entering genetic information in publicly accessible databases which are fixed in a dispositive form lead to criminal law application. For example, in early 2018, the U.S. law enforcement officials investigating the Golden State Killer case were able to find the suspect after submitting a request to GEDmatch (a public database) that encourages the users to upload genetic data together with personal identifiers. Without court permission, law enforcement authorities simply provided the genetic material from the crime scene. This trick helped the officers to find in the database a match for the person remotely linked to Joseph Di Angelo who was ultimately arrested for the crimes. Since

this successful way of investigation became widely known, some law enforcement officials have used similar methods to solve numerous cases, including several murders.

In most instances, the issues of genetic information use by law enforcement officials are stipulated in the form of imperative [peremptory] requirements. The abuse of authority in this sphere in the global legal practice has resulted in prohibition of the indefinite (unlimited in time) use of the genetic information of the arrested and (or) the convicted for crimes in judicial practice. For example, in the case of *S. and Marper v. United Kingdom* (Regalado: 2018), the European Court of Human Rights ruled that indefinite retention of DNA samples and profiles violates the right to privacy under the European Convention on Human Rights (D'yakov: 2020, pp.108-113).

As international legal practice shows, the choice between the imperative [peremptory] and/or the dispositive [discretionary] option in legal regulation of genetic research is determined by two key factors – the overall global trends with regard to a certain object of legal regulation (as, for example, in the instance of the imperative ban on human genome editing), and the peculiarities of the national legal system within which regulation takes place (the mandatory requirement for prenatal genetic screening in a number of instances established by the Israeli legislation).

Sometimes (e.g., in the instance of the proposed innovation in the Russian legislation with regard to genetic passports for the country's citizens) one can observe an obviously debatable nature of choosing an adequate norm in legal regulation of genetic research within the framework of the “dispositive - imperative” dichotomy.

CONCLUSION

The global legal community is currently looking for a consensus on the key issues of the imperative [peremptory] and the dispositive [discretionary] legal regulation of genetic research. The pace of development of genetic technologies is such that lawyers have to deal not only with the initial, but also with the subsequent gaps in law.

At this point in time, the focus is shifted towards a national, rather than an integrational solution to the problems of regulating genetic technologies. Time (as well as the people who are forming that time) will show how this situation will evolve.

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