Patent Regulation in the Field of Genome: Trends, Problems, Prospects

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ABSTRACT
The article explores the situation that has developed in recent years in the field of patenting the results of genomic and genetic research and manipulation. The author considers the main trends and possible ways of further development of relations and regulation in this area, including with regard to the role of Russia and the BRICS countries in the future world order, where genetic and genomic technologies and the results of their application will be (and partly already are) one of the most important values. The author analyzes the existing and possible forms of securing rights to these values for copyright holders, taking into account the difference between genetics and genomics (and the gradual blurring of this difference with the appearance of "designer genes"). The researcher concludes that there is currently no sufficiently developed, reasonable and workable alternative to the existing system of protection of rights to achievements in genetics and genomics, while maintaining the feasibility of searching for such an alternative, since the existing system provides unjustifiably large advantages to individual corporations and states that have managed to secure the largest possible amount of rights to achievements in genetics and genomics. The author analyzes some international acts that are designed to ensure a fair distribution of benefits between the owners of advanced technologies and the "suppliers" of the original genetic material. These acts are still undeservedly ignored in Russia; however, they gain new significance in the course of the ongoing "genomic revolution", which is based on the mass application of the CRISPR-Cas genomic editing method. The researcher suggests possible directions for concerted action by the BRICS countries on patent cooperation in relation to the results of genomic and genetic research and manipulation.
Keywords: *genetics, genomics, patenting, patent law, patent, BRICS*

1. INTRODUCTION

Anton Alexandrovich Ivanov said at a scientific conference in 2015: "We see well-known prospects in the rights to gene materials or the human genome, as well as other living beings. But this is a matter of the future" [1].
We can confidently say today: the future has come. This happened largely due to the fact that the new "breakthrough" CRISPR-Cas genome editing technology allows you to "cut" DNA at the right point and makes it possible to recombine it, replacing individual sections. Khambhati K., Bhattacharjee G., Singh V. [2] write that the CRISPR-Cas platform was conceived and developed initially "for idealistic purposes" as a tool for fast, accurate and cheap (this is important) diagnostics. However, unexpectedly, the CRISPR-Cas platform turned out to be incredibly attractive for commercial use as an "editor" of the genome. According to official data [3], in 2013-2016, about a billion US dollars were invested in American companies that develop and implement methods for the application of this technology. However, the world is not limited to the United States of America, and European, Japanese, and Chinese companies have also not been idle. It is not surprising that in 2020 the simplest genome editing kit using the CRISPR-Cas method can be freely purchased online for a hundred US dollars. The doors to the world of genomic editing have opened. But today, when the whole world is trembling because of a virus that has come from nowhere, the once asked question no longer seems rhetorical: will these doors turn out to be hellish gates?
Scientific publications on the legal regulation of genetics, genomics, genetic manipulation, and so on appear every year by the dozens in the Russian information space and by the thousands in the global information field. It is obvious that we cannot cover in a small article the entire vast topic of legal regulation in the field under study today, so we will focus only on the most general trends, problems, and prospects.

2. RESULTS

First of all, let us consider the current correlation of genetics and genomics from the point of view of patentability of the results. Mankind has been engaged in genetic research for a long time; questions of heredity and methods of coding the signs and functions of the body were developed in the 19th century. It should be noted,

however, that a gene as a structurally functional unit – a carrier of hereditary information – is the subject of a study of genetics. One of the main achievements of genetics is decoding the genome of one or another type of living organism, that is, the entire sequence of its genes and the information contained in them. For humans, this is about twenty-two thousand structurally functional units in twenty-three pairs of chromosomes. From about the mid-1970s, genetics reported the decoding of the genomes of increasingly complex organisms, and by the mid-2000s, they announced the decoding (albeit not completely) of the human genome.

Genomics arose much later than genetics as a scientific field that deals with materials obtained (decoded) in the course of genetic research. The subject of study in genomics is not a separate gene, but the interaction of genes with each other and, importantly, with external factors. If we distinguish genomics from genetics in a subject, then this subject will no longer be a gene, but a genome - in a simplified analogy, not a constructor part, but a specific model for assembly, and not a letter of the alphabet, but a word (the simplest genome of a virus, translated into usual units measuring the amount of information, takes a few kilobytes) or text (the decrypted human genome is about two million times more complicated than a virus – however, this information can easily fit on a not-so-capacious flash drive).

The question of the possibility of patenting individual genes, their location or sequence is extremely controversial both in science and in practice, and even within the same jurisdiction the practice can be diametrically opposite and change over time, as has happened, for example, in the USA over the past decade.

Of course, the author agrees with the position of V.P. Kamyshansky and A.I. Stanishevsky, who refuse patentability (and, at the same time, copyright protection) to a separate natural gene, even if it is extracted and purified [4]. Indeed, the issue of authorship of natural genes refers to the maintenance of either evolutionary biology or theology, and patenting such objects looks even less logical than patenting numbers and letters of the alphabet. “In view of this circumstance, it is not entirely clear how the gene could be patented in the USA” [4], – the same authors note, while recognizing, however, the possible patentability of technical solutions by which the extraction and purification of genes became possible, but no more.

It would seem that everything is extremely simple and obvious – in theory: the results of research in the field of genetics are not patented (unlike genomics). But life, as usual, is more complicated than any theory, and the illusion of evidence is dispelled at the first glance at judicial practice. Due to (alas) the actual predominance of the United States in the biotechnology market (which is also noted in the Federal Scientific and Technical Program for the Development of Genetic Technologies for 2019-2027), this practice is mainly North American – the rest of the world is oriented towards it.

Let us take a well-known case “Association for Molecular Pathology v. Myriad Genetics, Inc.” [5]. This case was considered in the United States in 2013 and it is often referred to in the literature [6-9] as a kind of milestone, a turning point after which patenting an isolated gene is considered unacceptable even in the US with its very liberal patent laws. Yes, the US Supreme Court concluded in this case that the selected DNA segment is not suitable for patenting, since it is a natural object (“a product of nature”). However, this conclusion was continued, allowing the patenting of modified or artificial DNA or DNA sections (“but cDNA is patent eligible because it is not naturally occurring”) – that is, including genes.

Just as an atom, which was once considered the smallest particle of matter, later turned out to have an internal structure (which later revealed its own internal structure – and probably this level is also not the last), so the gene is not at all a monolithic “constructor detail”. Therefore, by changing the elements of the gene, you can get something new (unknown from the state of technology), industrially applicable and possibly having an inventive level, which means that it is fundamentally patentable as an invention or at least an industrial design. We will continue the analogy with the alphabet: one cannot patent the letter “A”, but it can be performed in the original graphic design, modifying individual sections (just like in DNA). As it is known, the rights to fonts obtained in this way are protected, and in Russia they are protected simultaneously by patent law (subject to obtaining a patent for the font as an industrial design) and copyright (in contrast to the United States, where since 1976, the copyright on fonts does not apply) [10].

Moreover, if we look closely, we will pay attention to another interesting detail. In the same case “Association for Molecular Pathology v. Myriad Genetics, Inc.”, if you read carefully, the question of patentability of genes is raised through the prism of knowing the location on chromosomes and the sequence of elements of DNA-nucleotide molecules (bases). There is no doubt that a company that selected from the tens of millions of nucleotides contained on the chromosome, several thousand that made up the desired gene, and thereby identified the nucleotide structure and exact location of this gene (in a particular case, two genes associated with an increased risk of developing breast cancer and critical for diagnosing it), has done a great job - which, in fact, was initially recognized as deserving of adequate remuneration (in the form of an exclusive right certified by patents). Thus, the right to prohibit to other persons the reproduction (“right to exclude others from making”) of a part of a person’s DNA has been given to private persons, and if you approach formally, then reproduction in a natural way. The understanding of this did not come immediately and caused a well-known reaction in the form of recognition of the illegitimacy of such patents.

It turns out that patenting is quite possible even in the field of genetics: until the moment when patenting encroaches on the ability to use common (natural) nucleotide sequences or their closest variations (the patents of Myriad Genetics, Inc. also included the results of some mutations). Thus, we cannot say today unequivocally that “a gene cannot be an object of patenting”. An artificial or

significantly modified “designer” gene is not essentially excluded from the patentable objects, unlike a natural gene. Genetics is again gradually merging with genomics – from the point of view of patentability of the results, with the advent of the ability to edit a single gene or create new genes that have no natural analogues. Bioethics issues regarding such patenting should be considered separately.

If we turn from genetics to genomics, we will note an extremely important point in terms of the prospects for the development of our (and not only ours) patent (and, possibly, partially copyright) law. The process of creating objects that do not exist in nature is much easier today in genomics than in genetics. The CRISPR-Cas method and kits for self-editing of the genome were mentioned at the beginning of the article for a reason: manipulation of previously isolated geneticists and described genes was significantly facilitated. True, the recombination of genes in the genome is still carried out mainly by touch, through experimental enumeration. Humanity, armed with the CRISPR-Cas method (and others, by the way), reminds an apprentice of an electrician, who was given wire cutters, and forgot to teach the basics of electrical engineering. “I wonder what happens if you cut this out and paste this in?” – this is not the most effective (and not the safest, unfortunately) method of cognition; however, this method has one serious feature – mass character, when it leaves the scientific laboratory “to the people”. The notorious theorem on infinite monkeys has, as we know, not the only option: we can put not just one monkey with an infinite supply of time for a typewriter, but an infinite number of monkeys for randomly getting some Shakespeare play. It does not require multibillion-dollar investments and many experiments in laboratories (although no one has canceled this area of scientific research, of course, but a very serious addition to it appears): give millions of people the opportunity to inexpensively buy a genome editing kit, and sooner or later one of them will get a valuable result. This can be a virus that selectively destroys cancer cells, or a method of modifying germ line cells that gives a person absolute immunity to diseases, or at least a breed of decorative hamsters that is not found in nature. True, the opposite result is also possible – the accidental receipt of something malicious now no longer seems like a fantastic plot. However, it seems too late to put the genie back in a bottle. As O. Y. Fomina correctly notes when speaking about editing the human genome, “the development of genetic engineering in this direction can no longer be stopped” [11]. Once again, we will leave aside the issues of bioethics, although manipulation of the human genome is clearly separated from all others, both in the literature and in legislation, despite the absence of fundamental technical differences.

Thus, we are now on the threshold of receiving mass results of genomic manipulation – and we must be ready for this “ninth wave”. We believe that the following mechanisms are necessary in order not to be swept away by the “ninth wave”, but, on the contrary, to extract a useful effect, from the point of view of law:

1) Mechanisms of legal protection of the positive results obtained and encouragement of their authors (including, of course, material).
2) Mechanisms for preventing the receipt, as well as preventing the use of actually obtained dangerous or other negative results (for example, contrary to the principles of morality) – a kind of safety technique.
3) Mechanisms for selecting positive results and screening out negative ones, including criteria for such selection.

The possibility and expediency of using existing legal means to solve these problems – namely, patent law institutions (understood in a broad sense, since a significant part of cases will concern rights to selection achievements) – is quite obvious, if we approach the issue as pragmatically as possible, pursuing, among other things, the goals of reasonable economy. Of course, the solution of problems is not fully possible – for the second task, for example, it is clearly impossible to do without the tools of administrative and criminal law.

Do we want to reap the benefits of the genomic revolution? If so, we should give an incentive to create such fruits and use them in Russia. Take a look at the lists of authors of the most famous and, as they say, “breakthrough” articles on genomics [12, 13]: our compatriots occupy not the last place in these international collectives (it does not matter, they have a passport of which state). However, according to official data [3], the number of profile publications in Russia and the United States is correlated as 1 / 17,5, and in Russia and China as 1 / 9,3. The number of patent applications and patents for related developments in the world is growing exponentially during those seven years when CRISPR-Cas genomic editing systems have become widespread. Moreover, according to the data for 2017 [3], our country occupies a seemingly honorable place in the top ten - however, the gap with the leader (the United States) looks huge: 414 US patents fall on one Russian patent! Both these data and the ratio of the number of articles and patents, suggest a logical thought: well, we are lagging behind in scientific activity for a number of reasons – but why is the lag in the applied component so great (17,5/414)? Why do scientific achievements in the field of genomics so rarely turn into domestic patents? We believe that this clearly illustrates the consequences of the notorious "brain drain", and the trend towards active work of domestic scientists in foreign research teams – but also the general direction of the patent system and patent policy in the field of genome. Or, more precisely, state support and protectionism in foreign countries and, unfortunately, their absence in Russia until very recently.

Many countries believe, not unreasonably, that those who have captured the maximum rights to genomic objects today will profit from this over the next decades, and the state support provided to such initiatives, for example, in the United States, can be clearly seen. No matter how many famous scientists wrote in the “Financial Times” about “scientific interest combined with the desire to help the development of humanity” [14, p. 96] as a more powerful incentive for progress than patenting, at the same time, other researchers note the policy of “redistributing

economic benefits in favor of developed economies by receiving rents from consumers and economic agents in developing countries and reducing competition", which is being systematically implemented by a number of states [14, p. 99] through patenting the achievements of bioengineering (which, it seems, is not without reason called sometimes the "new imperialism" [15, p. 189]). Figures of annual patent payments of the developing countries in favor of copyright holders from the developed ones, cited by foreign researchers [15, p. 187], were impressive at the beginning of the 2000s – the scale has not decreased now, we believe.

Yes, it was possible to stop the process of undisguised division of natural objects (such as genes) between corporations through patent law, thanks to the triumph of common sense in law-making and judicial practice, as well as to some extent thanks to the efforts of the world community. However, "many developing countries believe that the intellectual property regime for wildlife objects was included in the global agenda by developed countries only when significant genetic resources were already withdrawn free of charge from developing countries (usually tropical countries where the main genetic resources are located)" [16].

We can call the adoption of the Convention on biological diversity in 1992 [17] (further – the Convention) at least some notable result of the efforts to protect the universal natural heritage from patent theft, in which Russia has been participating since 1995. "At least in some way" – because the Convention is neither "toothy" nor decisive. Thus, article 16 of the Convention ("Access to and transfer of technology"), which is of interest to us in the context of this work, obliges Contracting parties to "take appropriate legislative, administrative or policy measures to facilitate access to technology by the private sector... the joint development and transfer of these technologies" to developing countries. At the same time, a "patent noose", which allows, for example, producers of modified seeds, to condemn entire countries to starvation, is gently and delicately indicated: "patents and other intellectual property rights may affect the implementation of this Convention", in connection with which the parties "Cooperate in this area, guided by national laws and international law, in order to ensure that these rights contribute and do not contradict its objectives". No significant obligations. Moreover, the Convention confirms directly: biotechnology is a type of technology (that is, patenting in this area is possible – this moment, by the way, is relevant for Russian patent law with its definition of invention and utility model as technical solutions), and in the transfer of technology, "due to patents and other intellectual property rights", transfer conditions must take into account "sufficient and effective protection of intellectual property rights". In other words, we are not talking about any encroachment on existing patents and the existing system. In its original version, the Convention, though, formalizes the idea of the existence of "general knowledge", which cannot be transferred to anyone's specific hands to the detriment of others ("is not assignable to an individual, who can then enjoy rights of ownership" [15, p. 191]); however, it does not go beyond the semantic limits of Russian idiom "conversation in favor of the poor" [18]. However, the United States – the focus of the largest copyright holders – did not ratify the Convention anyway, just in case. No conspiracy theories – just business.

It should be noted that the researcher is now more interested in one of its additional protocols, the Nagoya Protocol, than in the main Convention [17]. It is also noteworthy that Russia has not signed this Protocol. A curious explanation was given for this in 2012 [19]: "This Protocol is not very relevant for us, it is more important for countries where there is a concentration of those genetic resources that are interesting in third countries – genetic resources located in poor countries and of interest to rich countries". But does the Nagoya Protocol really have a "purely applied, agricultural" focus, as was reported?

We can argue with that. In addition to general phrases about recognizing the importance of promoting equality and justice in developing conditions for the use of genetic resources, the Nagoya Protocol contains several ideas that the main patent holders are not ready to sign, to put it mildly. Thus, article 6 of the Protocol provides for nothing less than a permissive procedure for access to genetic resources (permission of the country of origin): "access to genetic resources for their use is regulated on the basis of the prior informed consent of the Party ... which is the country of origin of such resources". The entire Protocol is imbued with the leitmotif of fair distribution and benefit-sharing, and article 10 ("Global multilateral benefit-sharing mechanism") contains, to the dismay of American pharmaceutical and agricultural corporations in particular, not only a call to share, but also concrete proposals on how to distribute benefits fairly. In particular, it was proposed "joint ownership of the relevant intellectual property rights" (paragraph 1. j of article 10) and "joint ownership of patents and other relevant forms of intellectual property rights" (paragraph 2. q of article 10). It is clear that the powerful of this world (holders of patents for genomic designs based on biological material taken from natural sources on the territory of various countries) cannot do this – it would literally bring down their business plan for the next century. This may also explain, in part, the marked reticence towards signing the Nagoya Protocol on the part of states that do not wish to come into conflict with the main beneficiaries of the current order. An eight-year-old newsletter states: "The Nagoya Protocol is aimed primarily at resolving and preventing conflict situations, which is also not entirely relevant for Russia" [19].

The main problems of patent regulation in the field of genome, relevant both for Russia and for most countries of the world, are reflected in the described situation, as in a mirror. In fact, the world is at a crossroads now, as an epic hero. More precisely, like many heroes, because unity, unfortunately, could not be achieved and is unlikely to be possible for the objective political and economic reasons described above. As a result, each state is looking for its own "national idea" in the field of genome patenting. There are three main roads:

1) To patent the results of genomic research and manipulation (in the terminology of our patent law – "genetic constructs" [20]) and use all the possibilities of patent law in its current form to protect the interests of copyright holders. States that have strong scientific schools in the relevant field, traditions of commercializing scientific results, and developed industry go without a doubt in this way.
2) To deny the possibility of patenting objects obtained by genetic and (or) genomic manipulations, and not to provide legal protection to the interests of patent holders for such objects. Such experience in the world also exists, today – mainly in the states of South America [21]. It seems that this position allows rather accumulating their own potential and at some point going to the first group. There are many historical examples noted in the literature when countries starting as "technological pirates" become fierce champions of patent law, but only when their national industry and science begin to generate their own innovations [15, p. 186; 22].
3) Look for other ways, alternative to the existing patenting model, or without patenting as such, or, in the terminology of the Nagoya Protocol, "an innovative solution to regulate the fair and equitable sharing of benefits from the use of genetic resources". Today there are many projects of this kind, and they have strong supporters (for example, the well-known Manchester manifesto "Who owns science" [23]), including in Russia [14, 22]. It is proposed to use patent pools (as in the Nagoya Protocol), expanding the scope of compulsory licensing, differentiating prices in determining the size of license fees, paying remuneration for discoveries and inventions from special prize funds as tools for more efficient use of intellectual property and fair distribution of benefits – a fully open model of access to scientific achievement, finally [24].

Patenting genomic objects as objects with a special regime similar to the current regime of selection achievements can be a more moderate solution. The main difference is the greater freedom of the licensee to use selection achievements in comparison with the classical objects of patent rights. "For example, in the United States, under the regime of conservation of breeding achievements, seeds are allowed to be stored and replanted by farmers, as well as the use of protected varieties in subsequent breeding is allowed" [16].

However, it is unlikely that a separate state will decide to apply such a variant of patenting: this will deliberately put "its" copyright holders in worse conditions compared to those based on classical patent law. Therefore, the decision to switch to a special patenting regime can only be collective, worked out in the framework of international law. The same fatal flaw hinders and will hinder the implementation of all kinds of libertarian ideas, despite their undoubted fascination and attractiveness (especially for states where there are few patent holders). While the rules of the game on the global market are set by the main beneficiaries, the remaining states have few alternatives. In particular, it is time for Russia to decide in the field of rights to the results of genomic manipulations: either we are among those who share the "patent cake", or among buyers of crumbs at an exorbitant price. Unfortunately, Russia is currently in the position of catching up, having decided to move in the main stream, trying to get among the leading rights holders, but having started too late. In fact, we are starting now, when the Federal scientific and technical program for the development of genetic technologies for 2019-2027 has begun to be implemented (approved by the Russian Government Decree No. 479 of 22.04.2019). Time will tell how successful the attempt will be. I would like to see the search for an alternative to this "patent race" continue – just in case we do not succeed to the right degree.

The third option - the traditional Russian "own way" or "asymmetric response" – looks attractive, but, firstly, no one knows what it should be, and secondly, something alternative to the existing global system needs to be introduced into a rather big part of the planet right away so that the alternative is real. A purely national framework is narrow for this kind of decision – the relevant standards should be adopted at the level of at least an interstate association. Perhaps the BRICS or the EAEU will be able to play the role of such a union, but in the current form, their framework is still too narrow to effectively counter the current order.

First, China's participation in the BRICS as one of the truly leading powers today, not only in the development of genomic technologies, but also in securing rights to them, serves as an encouraging factor to a certain extent. However, we should not belittle the significance of Russia. So, N.A. Redchikova and M.V. Chikov, evaluating innovative activity in the BRICS countries, note the gap in the number of patent applications filed between Russia and China at a fantastic 1,286% – alas, not in favor of Russia, while in 1997 Russia was ahead of China by 19% [25, p. 44]. However, it is Russia that holds the highest rate of human capital development and research activity among the BRICS countries [26, p. 37].

Second, patent cooperation between BRICS members and others is slowly but surely being established. Thus, an attentive observer may find that invited guests from specialized bodies of states that are not members of the BRICS, as well as, very importantly, representatives of the Eurasian Patent Office (EAPO) have begun to take part in regular meetings of heads of intellectual property offices of the BRICS countries [27]. Meanwhile, the EAPO is a significant part of the former USSR participating in the Eurasian Patent Convention: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan (and, of course, Russia as a link). The addition of the post-Soviet states to the patent association of the BRICS countries would make it possible to extend the "rules of the game" developed by such an association to approximately a third of the territory of all countries of the world and almost half of the world's population. Such a scale automatically turns an attempt to change the world order from the demarche of a handful of outsiders to the patent revolution with the greater chances of success, the more stringent lines of behavior against violators will be followed by the largest copyright holders. The majority of

poor countries are more likely to fall away from the camp of supporters of strict patent protection of genomic research results if there is an alternative model based on the principles of fair distribution of fruits and benefits (previously indicated in the Nagoya Protocol). A similar alternative model may well be developed on the basis of BRICS+ (with the participation of the EAEU states) and is framed as a patent convention of BRICS+ in the field of genomic technologies open for third countries. The text of the Guidelines for intellectual property cooperation in the BRICS countries was agreed not so long ago as part of the work of the BRICS specialized working subgroup in the field of intellectual property (BRICS IPRCM). This is a kind of foundation for the development of subsequent documents of a more specific nature.

Another thing is that the proposal to introduce changes in the field of legal regulation of the grounds and procedure for the use of genomic technologies and objects will not be successful without the proposal of the technologies themselves and (or) their fruits – in contrast to the products of current world scientific and technological leaders. The combined efforts of the BRICS countries can lead to getting the necessary developments in the foreseeable future. India demonstrated something similar not so long ago, having established the mass production of inexpensive analogues of American and European pharmaceutical products and their implementation according to the so-called Jan Aushadhi Scheme (Public Medicine Scheme) [28]. It is important, however, that the main owners of technologies do not succumb to the temptation to move to the camp of patent rights zealots, as once happened with Switzerland, the United States, Japan and others [15, p. 186; 22].

3. CONCLUSION

It appears that the use of BRICS as a platform to build a better future for all humanity, not only for patent holders, meets the role and prospects of BRICS in the contemporary international system, as claimed in the Concept of Russia's participation in BRICS (p. 8): to reform an outdated international financial and economic architecture that does not take into account the increased economic weight of emerging market economies and developing countries [29].

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