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The Law of a Technogenic Civilization to Face Technological Dehumanization Challenges

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Abstract

Law as a regulatory system based on the principle of formal equality in freedom is a social phenomenon immanently inherent in a technogenic civilization with its cultural matrix, in which "gene" of techne (skill based on knowledge) was rooted. The specifics of the current stage in the technogenic civilization development are determined by NBIK technologies, NBIK technologies, which contain not only tremendous opportunities to improve the quality of human life, but also no less large-scale dangers of dehumanization, due to their intentions on the posthuman perspectives. The need to resist the destructive potential of these technologies in order to keep the techno-humanitarian balance, which still protects humanity from self-destruction, requires the mobilization of all socio-normative resources, the most important of which is law. However, the problem is modern law, being primarily a system of human rights, is not able to prevent threats to future generations and humanity as a whole. This is especially clearly seen in the example of research and technologies for inherited editing of the human genome, which development cannot be channeled into the mainstream of global legal regulation. The international norms of "soft law" and the world academic community self-regulation can no longer restrain technological expansion into human nature. An attempt to solve the problem along the path of a post-secular turn in the hope that religious consciousness will become that saving spiritual resource, which help humanity to keep its technological power within the proper boundaries, is unlikely to be successful due to the differences in religious anthropologies inherent in different types of religious ideologies. Therefore the task

is to develop such a new approach to law understanding that goes beyond the technogenic civilization's spiritual matrix, which, on the one hand, would preserve the basic guarantees of individual freedom, and on the other, would integrate the idea of the rights of future generations.

Keywords

law, technogenic civilization, NBIC-technologies, editing the human genome, artificial intelligence, dehumanization, human rights, solidarity, future generations.

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Introduction: concepts and theoretical and methodological basis of the analysis

The formulation of the subject of the study contains ideas in need of clarification. This first of all applies to the concept of the *technology-driven civilization*, included by academician Vyacheslav Styopin in his typology consisting of two main types of civilization: traditionalist and technology-driven. The distinctive features of the technology-driven civilization, whose cultural matrix, since its inception, has some sort of *techni* "gene" (that is knowledge-based creative skills) embedded, include the following: the understanding of human beings as the creators transforming the world around them; the ideal of progress, understood as the priority of innovation over traditions; the approach to nature as the object of transformations and the reservoir of resources for action; the cult of scientific rationality; the ideal of the autonomous personality; the idea of power, not so much as power over other human beings, but as power over natural and social objects [Styopin V.S. 2017: 185].

If one tries to identify among these characteristics the most essential (vital, sense-making) one, this is perhaps "innovativeness [of the technology-driven civilization], [its] perennial and steadily accelerating stream of pioneering research and development projects, which form the basis and matrix of universal changes" [Maslov V.M., 2014: 871-875]. The modern technology-driven civilization, with its tremendous drive for innovation, defines the main development path for humanity — the course of the journey that has been joined, with different degrees of success, by those countries and regions previously had pursued the traditionalist model of civilization.

Another thing in need of elucidation is the concept of "law," the attempts at theoretical understanding of which have generated a wealth of concepts. This writer will draw on academician Vladik Nersesyants's idea of law as a system of norms epitomizing the ontological legal principle of formal equality — equality of free people [Nersesyants V.S., 2002: 3–15]. It is this approach that has the largest degree of congruity with the social phenomenon that can be defined as law of the technology-driven civilization: a human being's creative freedom is ultimately the main resource for the progress in science and technology. Unlike the other normative systems (moral, religion, customs), which due to their very nature gravitate towards the traditionalist civilization, law, as a measure of a human being's freedom, is a product of the technology-driven civilization, as well as a stimulus for its development and a guarantor of its safety.

The word "technology," too, is often interpreted differently by different parties — its present-day academic usage is very far from the definition proposed in UNESCO's Recommendation on the Status of Academic Researchers (1974), according to which "the word 'technology' signifies such knowledge as relates directly to the production or improvement of goods or services"[1]. Presently the word "technology" can be applied to all types of human activities (including the social technologies) people can carry on in order to transform or manipulate their surroundings. The present article, however, addresses only the so-called high technologies in the NBIC-convergence framework because it is nano-, bio-, info- and cogno-technologies in their synergetic unity that define the essence and distinctiveness of the present stage of the technology-driven civilization's development.

As for the term "technological dehumanization", because of its conceptual crudeness and the polysemy of the pivotal term "dehumanization" [Haslam N., 2006: 252–264], it needs gnoceological legitimation. The introduction of this term into academic discourse is necessary for gaining a thorough understanding of the qualitatively new, post-human character of the 21st-century high technologies, which change not only human beings' surroundings but also human beings themselves — their consciousness and mental and physical characteristics. As they achieve positive results in medical treatment, improving living standards and saving individual lives, in relation to humanity as a whole these technologies, intervening in human subjects, may ultimately produce a considerable cumulative dehumanizing effect.

[1] Available at: http://hrlibrary.umn.edu/instree/researchstatus.html; also: https://en.unesco.org/themes/ethics-science-and-technology/recommendation_science/evolution, https://unesdoc.unesco.org/ark:/48223/pf0000114040.page=166) (accessed: September 29, 2021)

Gaining a thorough understanding of law as a phenomenon of the technology-driven civilization should include an analysis of law as the key socio-normative guarantor of safety of technological progress. For illuminating the role and significance of law as an internal protective mechanism of the technology-driven civilization, a useful analytical tool to apply is the concept of techno-humanitarian balance developed by Akop Nazaretyan. According to this concept, the more powerful man-made military and industrial technologies are, the more sophisticated methods of cultural (socio-normative first of all) regulation are needed for preserving the body public. Culture, writes Nazaretyan, "having been tempered in the crucible of dramatic cataclysms, had been improving its tools of control over natural aggressive impulses and so adapted the man to the growing instrumental power." He formulated and tested his idea on the basis of a historical analysis of causes of anthropogenic crises and disasters throughout the history of humankind and on the basis of an estimate of the fluctuations of the fatality rates (that is a proportion between the average number of murders and the population size at a given time period) — these rates steadily dwindled as military technologies became more sophisticated and the population sizes increased. Nazaretyan's analysis shows that societies which managed to mobilize the humanistic elements of reason in order to defuse the destructive potential of anti-humanistic rationality came out winners in historical competition whereas the others "were weeded out of the historical process, as they destroyed the natural and/or organizational foundations of their existence" [Nazaretyan A.P., 2015: 107, 116].

In a situation when "the breath-taking speed of technological development that may very easily run out of control" [Weizsäcker E., Wijkman A., 2018: 6] is becoming, as stated in the anniversary presentation of the Club of Rome, an increasingly more far-reaching and systemic problem of modern society, the vital question is whether the technology-driven civilization is constitutionally capable (or incapable) of handling this problem using its own resources. Because, as civilization evolved — and, concurrently, on the one hand, the need for creative freedom grew, and on the other, the risks of man-made disasters grew as well — law has been assuming, to an ever greater degree, the functions of the regulator, edging out the other socio-normative regulatory mechanisms, so the vital question now is this: is it possible, using legal tools, to prevent the consequences of technological dehumanization that pose risks to humanity? So this is the lens through which this writer is going to look at the issue at hand. The main problem, meanwhile, consists in the fact that law, essentially a product of the technology-driven civilization, is the main source of dangers this civilization

may face. If, according to Gödel's incompleteness theorems, one cannot provide a complete and consistent description of a system staying within this system, the question begs itself: is it possible to solve a system's problem using only this system's immanent resources?

1. Law as a phenomenon of the technology-driven civilization

In order to understand the nature of law as a phenomenon of the technology-driven civilization, one should take a look at the origin and development of law. In the context of the issue under review, the main question pertaining to the genesis of law is whether law, at the stage of its gestation, was the result of the man's social creative work (in which case we indeed can claim that law is the product of the creativity- and innovation-oriented technology-driven civilization) or whether it emerged as something "natural," something given from the outside, something basic for that place and time — the element which, as proponents of natural law argue, "is the sole and incontestable primary source of legal meaning and the absolute legal touchstone for all man-made norms, rules and laws" [Nersesyants V.S., 2006: 794].

Addressing the issue at hand, this writer assumes that the approach to law as a special social phenomenon reflecting a certain essentiality implies that law had this essential characteristic already at its inception [Nersesyants V.S. 2006: 63]. This means that (contrary to what is generally assumed) law was not a part of a syncretic monistic norm that spawned the primitive society's system of relations, which included rudiments of law, morality and religion, as well as tribal customs. This view on the genesis of law is corroborated in the works of a number of anthropologists who distinguish law as an essentially social phenomenon from the naturally formed customs regulating the relations of blood kinship. These researchers, moreover, they emphasize a circumstance that is vitally important for our analysis — society and law emerged at the same time. From this vantage point, legal equality was not at all born from "brotherly" distribution of food within a clan but from essentially social mechanisms of containment of sexual instinct, such as the establishment of an intragroup taboo on incest and the enforcement of this taboo by creating a clan consisting of two groups and a system of matrimonial exchanges between these groups, which were, historically, the first subjects of egalitarian social relations[2].

[2] This writer refers to a situation when a clan is divided into two equipollent groups, which develop a practice of swapping so called "marriage partners," mostly brides.

The first in the history of humankind, this instance of social engineering, which was a product of the colossal exertion of the primitive man's intellect and will, became, according to Lévi-Strauss, a first step in the protohumans' journey from the world of nature to social world: "Prohibition on incest… is the basis of human society" [Lévi-Strauss C., 1985: 19]. The incest taboo was instrumental in protecting the nascent humankind from the danger of self-destruction, which was conditioned by the absence of instinctive jammers of intraspecific aggression[3] in humans as a distinctive biological species; this taboo also contributed to preventing members of clans from self-destruction in the course of the struggle for satisfying sexual instinct.

Another product of this taboo was the creation of collective subjects of interaction who communicated with each other on a formally egalitarian basis. "Social interactions in the system of two-group clans was based on an equipoise of clans. Preservation of each clan was contingent on preservation of this equipoise. Each clan considered its counterpart *as different but equal*… No single group knew how to keep another group under its thumb and an attempt to shift the balance so as to benefit one of the clans would have been disastrous for the entire community" [Shalyutin B.S., 2011: 18]. The formation of the two-group clans became the main driving force both in the formation of society (because each of the communities' groups was thus provided with a collective image of the Other necessary for producing the groups' self-identification) and in the formation of law (because in the process of what was essentially law-based exchange the nascent humankind was acquiring and enriching its experience of law-based communication).

Sure enough, the approach to law as the result of human beings' creative efforts to contain the destructive aggression inherent in their biological self should not be understood as a negation of the fact, already proven by biologists [De Waal F., Ober J., 2006: 140-160] and evolutionary psychologists, that empathy and reciprocity became incorporated in human genes in the course of the evolution. Moreover, this genetic predisposition was the source of the capacity for rational, that is consciously reciprocity-based approach to solving problems arising out of conflicts within clans. The mutual penetration of natural and social elements, typical for biosocial evolution, was instrumental in addressing the most difficult challenges of the evolution — on the one hand, it was necessary to preserve humans' intraspecific aggression, the quality which is, according to experts, the key source

[3] According to the prominent ethologist Konrad Lorenz, this property of humans as a species could have destroyed them had the human mind not proved itself capable of coping with the dangers associated with this property. See [Lorenz K., 1994: 200–220].

of an individual's creative energy, and on the other hand, humans' most dangerous manifestations had to be blocked. From this postulate, however, one cannot infer the natural character of the human rights, contrary to Fukuyama's and other thinkers' argument. In this natural state human beings were not yet different from animals: they became humans precisely through their conscious creative efforts to contain their natural instincts.

Despite the universality of the initial stage of the formation of society and, synchronously, of law, the further evolution of law as a carrier and expresser of human being's creativity proceeded differently in different regions of the world. For a number of historical reasons, societies living by the principle of formal equality of free people were mostly concentrated in Western Europe, where equality contributed significantly to the birth of the technology-driven civilization. Of great importance in the evolvement of the technology-driven civilization was antique philosophy, which laid the foundation of rationalist European culture, with its orientation at people's creative, transformative activity and its Christian spiritual tradition, which "was some sort of a mediating force between antique and new European cultures" [Styopin V.S., 2011: 254].

The key role in the process was played by the Christian dogma, embedded in the West's spiritual matrix, whereby the man was made in the image and likeness of God; in Catholicism, this dogma expressed the man's aspiration to understand God by understanding the man made in His image and likeness. This is a major point of difference between Western theology and the Eastern traditional approach to the dogma about the man's likeness to God — the approach based on the premise "that the Revelation tells us about God and only after this, tells about the man and finds in him that what corresponds with the image God," with the result that the man's image remains "incomprehensible because reflecting the entirety of his Prototype, he also must be as incomprehensible as He is" [Sinelnikov S.P., 2010]. The Catholic idea that God can be comprehended through the man and that it is possible to consider human actions as "some sort of a small-scale reproduction of the acts of creation" [Styopin V.S.: 2011: 256] was later developed by Protestant thinkers. In Western societies, these core beliefs contributed to the gestation of the ideas of people's freedom in public life, whereas the Orthodox Christianity catechized the man into the importance of spiritual freedom from sin [Sinchenko G.Ch., 2000: 16].

The Western traditional exegesis of the Christian dogma of the man's likeness to God was reinforced with the belief in rationality of the Creator, "who endowed his Creation with consistent physical laws" [Woods T., 2010:

87]. And although Peter Abelard's proud statement "I seek to understand in order to believe" — which stood in contrast to the concept "I believe in order to understand," prevalent at his time — was gaining acceptance with difficulty [Levandovsky A.P., 2005: 6-13], ultimately it became incorporated into the West's spiritual matrix, creating a most favorable environment for the development of sciences. Another important factor contributing to the process, and likewise closely related to the mentioned Christian dogma, was the idea of equality of people, understood in a far broader sense than the limited equality of the free citizens of the ancient Greek city-states. This contributed to the significant strengthening of law as a normative regulator based on the principle of equality of free people, and since the start of the modern era law has been steadily sidelining religion and morality in the hierarchy of socio-normative regulators. Law-based path of humanity's development, which was present in social practices and conceptualized in the works of the Modern Era's philosophers, for whom natural law "was already originating not from the universal law of nature or divine reason but from the very nature of the man" [Romashov R.A., 2021: 16], — this law-based path brought human beings the creative freedom necessary for scientific and technical progress and later, for scientific and technological progress.

Law meanwhile not only created an environment suitable for the development of sciences and technologies: performing its initial function, it continued to serve as a safeguard against humankind's self-destruction that could take place in the wake of yet another breakthrough in science and technologies. All through the history of the origination and development of the technology-driven civilization, the growing power of the new technologies was compensated by improvement of socio-normative (first of all religious, moral and legal) regulators, and this preserved the balance between technical and humanitarian elements keeping the civilization from destruction. A good example of such beneficial transformation of socio-normative regulators is the evolvement of religious tolerance in Europe in the aftermath of the Thirty Years' War (1618-1648). Herefrom, according to Paul Ricoeur, originated the ideology of liberalism, which affirms the idea of tolerance, proclaimed in the New Testament by Apostle Paul, "as a positive value of a higher level than religious beliefs, which are different from each other" [Ricoeur P., 2005: 81]. Another equally important result of this lengthy and deadly war was the establishment of the principles known as Westphalian sovereignty, which ushered in the new era in international law. Intrastate social conflicts at that period of the evolvement of capitalism, too, were handled within a legal framework, which facilitated the elimination of class barriers and the release of the creative energies of the nascent bourgeoisie.

The French Declaration of the Rights of Man and of the Citizen (1789), a milestone in the evolution of law, can also be considered as one of the results of the Thirty Years' War: as Nikolai Berdyaev wrote, quoting Georg Jellinek, "this declaration originated in religious communities of England, begotten of the religious recognition of the freedom of consciousness and the definitive importance of the human individual, who sets limits on any power of the state. From England the Declaration of the Rights of Man and of the Citizen was brought to America and only after it, to France" [Berdyaev N.A., 1990: 288]. As for America, the text in question is the Declaration of Rights, adopted in 1776 by the legislature of Virginia — the document which, in the context of our analysis, merits special attention: proclaiming natural human rights, it is the first historical document bringing up the idea of the rights of future generations, which is receiving the appreciation it merits only now, in the context of the advent of the technologies capable of intervening in human subjects. Section 1 of the Declaration states: "…all men are by nature equally free and independent and have certain inherent rights, of which, when they enter into a state of society, they cannot, by any compact, deprive or divest their posterity…"[4] The realization of the ideas set out in these groundbreaking acts of expression of people's will facilitated the evolvement of the modern system of law as a normative form of people's freedom and the evolvement of law-based democracy as an institutional form of freedom: "Sweden in 1809 and Holland in 1815 followed the English model of incorporating the concept of natural rights into the constitution of a monarchy; other nations copied the American model of a republic having the preservation of men's natural rights as its raison d'être" [Cranston M., 1975: 12].

In the 20th century the system of international law received a powerful stimulus from the two world wars whose experiences were reflected in the Covenant of the League of Nations (1919), the Pact of Paris, otherwise known as the General Treaty for Renunciation of War as an Instrument of National Policy (1928), and the Charter of the United Nations (1945), which formalized the prohibition on war as an instrument of settling disputes and allowed to use the force of arms when sanctioned by the UN Security Council. The deliberations about the anti-legal experience of the totalitarian regimes going on at that time considerably strengthened legal elements in public life and governmental affairs, a process resulting in the adoption of the Universal Declaration of Human Rights (1948) and the related international treaties elaborating on its provisions. Many states

[4] Available at https://www.archives.gov/founding-docs/virginia-declaration-of-rights (accessed: January 10, 2020)

incorporated into their postwar constitutions the array of human rights contained in the mentioned documents. This array is based on the set of humanistic values of natural law, the product of the merging of the antique understanding of law as a just measure-for-measure retribution and the Christian moral idea of justice as mercy[5]. Although the doctrine of natural law by now[6] has gone through numerous transformations in keeping with the times, it still combines these conflicting regulatory principles[7].

Up until now humanity, using the international non-proliferation agreements related to nuclear, chemical, biological, radiological, etc. weapons of mass destruction, has succeeded in keeping the situation under control. In the current context, however, these intergovernmental agreements can no longer guarantee security because new actors are getting hold of the technologies of the production of weapons of mass destruction. Technologies are a form of knowledge and skills whose reproduction is much cheaper than their creation. According to scholars of life-saving technologies, this peculiarity makes technologies what might be called a carrier of collective interaction, which becomes the main motor of history [Podlazov A.V., 2018: 39-63]. But this feature also makes these technologies easily available life destruction instruments. This peculiarity becomes especially dangerous in the present context of polarization of wealth[8], when corporations and even individuals have been given the opportunity to lay their hands on resources which are beyond society's control and which "are just as big as or even larger that the resources controlled by the state"[9].

One of the most vivid examples of this danger is international terrorism. The global terrorism threat presented humanity with a very difficult moral dilemma — on the one hand, there is the idea of law as a form of free-

[5] Tellingly, some Western authors call the rights set out in the Universal Declaration of Human Rights "moral rights" (Cranston M., 1975: 97].

[6] "The doctrine of natural rights by now… has shed its excessive axiomaticity and straightforwardness but still has the potential to develop along its traditional lines" [Romashov R.A., 2021: 51].

[7] The most vivid example of this is the interpretation of the right to life which rules out capital punishment.

[8] "Global income distribution has thus changed in a remarkable way. It was probably the profoundest global reshuffle of people's economic positions since the Industrial revolution… The most interesting developments, though, happened among the top quartile: the top 1%, and somewhat less so the top 5%, gained significantly, while the next 20% either gained very little or faced stagnant real incomes" [Milanovic B., 2014: 15].

[9] "New Rules or No Rules." 11th Annual Valdai Discussion Club Meeting Participants' Report. Available at: https://valdaiclub.com/a/reports/new_rules_or_no_rules_xi_annual_valdai_discussion_club_meeting_participants_report/ (accessed: September 29, 2021)

dom inherent in the spiritual matrix of the technology-driven civilization, and on the other, there is the need to limit this freedom for security's sake. Whereas previously this perennial problem of humankind was handled by separate players on their own terms, in the modern society of global risk its handling became very much a public legal matter. The question in need of an answer, meanwhile, is this: in order to guarantee safety of those who are averse to risks, is it justified to limit the freedom of those who are willing to risk their safety for the freedom's sake? Its implications reaching far beyond the problem of terrorism, this question, which modern society has yet to answer, has taken on special urgency in the context of COVID-19, when humankind has to decide whether one should "exchange health protections for basic rights,"[10] if what is at stake is far more than one's own health.

In the context of our analysis, the most interesting aspect of the problem of legal regimes during a pandemic is not so much the lockdowns (on which most legal debates has been focused) but the extensive use, by the states, of digital tracking of contacts and digital observation of citizens' health. And since it has been discovered that such form of control is simple and efficient (the People's Republic of China has gone especially far along this path), there is a danger that these practices will remain a norm even when the COVID-19 pandemic is over. The need to address this danger for the sake of protecting human rights and freedoms was brought up, in particular, in the Joint Statement on Data Protection and Privacy in the COVID-19 Response, issued on December 18, 2020, and signed by several UN organizations[11].

The pertinence of this formulation of the problem was demonstrated especially clearly in the book "COVID-19: The Great Reset," a treatise co-authored by the World Economic Forum's founder Klaus Schwab and released at the height of the pandemic: the authors argue that even when the pandemic is over, "nothing will ever return to the 'broken' sense of normalcy that prevailed prior to the crisis because the coronavirus pandemic marks a fundamental inflection point in our global trajectory… the world as we knew it… is no more, dissolved in the context of the pandemic" [Schwab K., Malleret T., 2020: 11]. According to Schwab, who is one of the world's most influential experts, the pandemic is a "window of opportunities" for creating a new world where nation states will be replaced with

[10] Cortés-Arbeláez A. Pandemic and States of Emergency: A Comparative Perspective. 2020. May 22. Quoted: [Varlamova N.V., 2020: 25].

[11] Available at: https://reliefweb.int/report/world/joint-statement-data-protection-and-privacy-covid-19-response (accessed: September 29, 2021)

transnational companies, which, Schwab believes, will carry the bulk of social responsibilities. Klaus Schwab's previous tome, "The Fourth Industrial Revolution," in which he shows himself not only as a globalist but also as a transhumanist, gives us a good idea of the type of world that is supposed to be built after the "great reset" (or, in a more apt translation suggested by some, "the great resetting of the counter to zero"). The pandemic, Schwab argues, has accelerated the transition of the technology-driven civilization to the fourth industrial revolution with its convergence of NBIC technologies, promising radical changes to humankind.

Called by many a globalism manifesto, this book appears to have marked the beginning of a qualitatively new stage of the late modernity, straightforwardly outlining the ominous contours of a post-human reality that may arrive in the foreseeable future. Another development of the last decade, looking equally ominous in the context of our analysis of the genesis of law, has received much less notice globally. In 2014 Germany's National Ethics Council recommended that the ban on incest be lifted, arguing that "the fundamental right of adult siblings to sexual self-determination is to be weighed more heavily than the abstract idea of protection of the family."[12] The matter at issue here of course is not the call to lift a criminal ban on incest (in many countries incest is not regulated by criminal legislation) but the argumentation aimed at convincing the public of social acceptability of the elimination of the age-old taboo which once set in motion social history of humankind. This approach, designed to destroy the institution of the family, has a dehumanizing potential because the family is the place where people restore their psychological resources necessary for preserving the potential of humaneness which so far has kept humankind from self-destruction. The fact that this issue has been broached now is probably not accidental: destruction of the foundation built by evolution into human civilization is one of the preconditions for transition to a post-human future.

2. Law and the challenges of the technology-driven civilization

For all the seriousness of the abovementioned problems, which arise as destructive technologies evolve, humankind so far has been able to preserve the vital balance between technological and humanitarian elements, in large measure because the risk of humanitarian element being margin-

[12] "Incest Ban at Odds with Sexual Self-Identification" (Zapret intsesta narushaet pravo na seksual'noe samoopredelenie). Available at: URL: https://russian.rt.com/article/51928 (accessed: February 5, 2021)

alized was obvious. The 21st-century newest NBIC technologies, however, are first of all creative, rather than destructive, technologies, the ones that give people hope for overcoming the environmental crisis, transitioning to personalized medical care, increasing life expectancy, advancing in most diverse spheres that use artificial intelligence technologies, becoming capable of creating a new world through controlled manipulation of atoms and molecules and of improving the quality of individual and public consciousness, etc. — all these alluring prospects serve to obscure the post-human nature of these technologies which are, in essence, "forms, methods for putting post-human into practice" [Maslov V.M., 2014: 872].

Although many of the posthuman applications of NBIC technologies are yet theoretical, there are already some alarming episodes of their practical application. Thus, the prospect of organ printing from stem cells utilizing 3D nano-printing technologies is still a theoretical option but nanorobots in medicine are already a reality, so the anxieties about their possible unsanctioned incorporation into human organisms are not unwarranted. The technologies of genome editing of embryos, as was noted by one of the creators of the method and Nobel Prize winner Jennifer Doudna, still cannot make "the designer children" intelligent and good-looking, although even now they can be used for augmenting an organism's endurance, developing the capacity for sleeping less than usual, etc.[13] — enhancing the qualities giving a competitive edge in life. Similarly, one can say that although neurotechnologies still cannot control what is going on in the brain, brain scans can expose individuals' political orientation — show whether it is liberal or conservative — with more than 70% accuracy [Kosinski M., 2021]. And it is not only states but private persons as well who can become digital dictators utilizing these innovations.

Besides, in the foreseeable future control over information, as was noted by Israeli historian Yuval Harari in his presentation at the World Economic Forum, will enable the world's elites to do something more radical and dangerous than establishing a digital dictatorship: biological engineering and information technologies will make them better informed about any single individual than this individual's family. "If these matters are not regulated, a tiny group… will set the course of life on the Earth."[14] Because presently the practical post-human potential of NBIC technologies is most obvious-

[13] Available at: URL: https://batrachospermum.ru/2020/10/daudna-genomes-ethics/ (accessed: September 29, 2021)

[14] Available at: URL: https://trends.rbc.ru/trends/futurology/5e2ef4499a79474925acdf08 (accessed: January11, 2021)

ly realized in artificial intelligence technologies (which experts consider as metatechnologies of the NBIC complex) and in human genome editing biotechnologies, this writer wants to take a close look at these fields of modern technoscience. "Artificial intelligence" (AI) refers to "technological systems which have the capacity to process information in a way that resembles intelligent behavior, and typically includes aspects of reasoning, learning, perception, prediction, planning or control"[15]. It is generally considered that there are three dangers of dehumanization associated with AI: humans losing control of AI; the likelihood of creating an AI programmed to deliberately cause harm; the risk of discrimination against different social groups — discriminating patterns can be built into "algorithms by reflecting (intentionally or not) the programmers' prejudice[16] or discriminatory stereotypes inherited from predecessor software" [O'Sullivan S., 2019: 9].

When considered individually, each of these risks does not seem very threatening, and yet, a combination of them in a technology can be threatening to the very foundation of human coexistence. AI emotion recognition technologies are one such example. As demonstrated by China's experience, which was analyzed recently in a report of British human rights group Article 19, the introduction of these technologies starts with such seemingly innocuous projects as assistance to law enforcement[17], but very quickly the scope of use expands under the enormous pressure of interested parties such as the government and businesses.

For all the abundance of public and academic discussions of ethical and legal aspects of AI — and this subject has grown in prominence in recent years — experts note that the current global problem is "the practically complete absence of legal and technical regulation of the basics, conditions and distinctive features of the research and development, launch, function-

[15] First Draft of the Recommendation on the Ethics of Artificial Intelligence (I(2)), prepared by UNESCO's expert group, in line with the decision of UNESCO's General Conference at its 40th session (40 C/Resolution 37), in March 2020. Available at: https://unesdoc.unesco.org/in/documentViewer.xhtml?v=2.1.196&id=p::usmarcdef_0000373434&file=/in/rest/annotationSVC/DownloadWatermarkedAttachment/attach_import_0982366e-6c20-418f-9317-c09866b9b0e9%3F_%3D373434eng.pdf&locale=ru&multi=true&ark=/ark:/48223/pf0000373434/PDF/373434eng.pdf#page=1&zoom=auto,-16,850 (accessed: September 29, 2021)

[16] Thus, a significantly larger share of males among software developers can result in the creation of software which latently discriminates against females.

[17] Emotional Entanglement: China's emotion recognition market and its implications for human rights. Published by ARTICLE 19 in January 2021. London, 2021. P. 18. Available at: https://www.article19.org/wp-content/uploads/2021/01/ER-Tech-China-Report.pdf. (accessed: April 16, 2021)

ing, integration with other systems, and control over the utilization, of AI technologies [Ponkin I.V., Redkina A.I., 2018: 93]. Moreover, appropriate international ethical recommendations have yet to be produced. This is why in March 2020 UNESCO set up a group of experts, which by September 2020 produced a first draft of recommendations on ethical aspects of AI. Remarkably, the text in question is not a normative legal document but only a recommendation focused on AI's ethical aspects: the text's authors emphasize that this is only a framework document, which "finds its basis in ethics, as well as human rights [and] fundamental freedoms."

As it appears, the actors who initiated the creation of these recommendations took into consideration the long experience of working on ethical and legal regulation of genome technologies — an undertaking that has yet to produce a global legal act, although the creation of such instrument was declared as a goal already at the initial stage of the international Human Genome project. But for all the importance of the challenges related to AI technologies, as Yuval Harrari noted, these technologies are "just stimulants for your imagination. What we should take seriously is the idea that the next stage of history will include… fundamental transformations in human consciousness and identity. And these could be transformations so fundamental that they will call the very term 'human' into question" [Harari Yu., 2019: 491]. Genome editing technologies, which even now can directly intervene in human subjects, carry the most obvious risks of dehumanization. Interestingly, modern neo-Marxists invoke these technologies in their analyses of the essence of the present stage of capitalism, whose main distinction is the fact that knowledge, at this stage, is regarded already not as an instrument of production but as means of reproduction of biological and social life[18] .

The world's leading geneticists, who once initiated the international project of human genome sequencing, took great efforts to set in place a system of socio-humanitarian guidance for their research. Moreover, beginning from the 1980s, that is concurrently with the start of the international Human Genome Project, the Council of Europe developed and adopted a series of recommendations on genetic engineering, on utilization of embryos and human biomaterials for diagnostic, therapy and scientific research, on genetic testing for medical purposes, etc. These recommendations were later used in the preparation of the text of the Convention for

[18] The situation when capital controls knowledge, writes Antonella Corsani, "can ultimately lead to the situation when it is possible to decide whether or not to grant the right to live. Pharmaceutical industry, for instance, prefers research into rejuvenation methods to fight against tropical diseases" [Corsani A., 2007: 130].

the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as the Convention on Human Rights and Biomedecine), which was opened for signature in 1997. Later, however, only three binding protocols complementing the Convention were adopted[19] while the rest of international documents in this area are "soft law," that is texts of a declarative and recommendatory nature[20].

The attempts to direct along legislative lines socio-normative regulation in the area of human genome editing research and clinical trials have faced serious resistance due to the differences in sociocultural traditions in different regions of the world (first of all the differences in religious anthropology, the most vivid example of which is different interpretations of the ontological status of human embryos), as well as the extraordinarily fierce competition in this field: countries compete for biosafety and their citizens' living standards; transnational corporations compete for markets for drugs and technologies; and scientists compete for scholarly prestige. It is precisely the striking advances in human genome editing made by Chinese scientists that caused British authorities in 2016 to allow genome editing of 2-week-old human embryos in vitro, provided they would not be implanted into a woman's body.

The desire to keep up with the competition undoubtedly played some role when Britain's Nuffield Council on Bioethics (a civic organization respected in the academe) published in 2018 a report stating that heritable genome editing interventions may be allowed, provided they are "consistent [with] the welfare of the future person; and they should not increase disadvantage, discrimination or division in society"[21]. Some experts, meanwhile, believe that the report "leaves open the possibility that such technologies could be misused for cosmetic purposes" and "breaches an international consensus in a way that increases the risks of irreversible genetic alterations and new forms of inequality" [Dickenson D., 2018].

[19] Additional protocols on human cloning ban (Jan. 12, 1998), biomedical research (Jan. 25, 2005), and genetic testing for health purposes (Nov.27, 2008).

[20] This is first of all the Universal Declaration on the Human Genome and Human Rights (1997), International Declaration on Human Genetic Data (2003), United Nations Declaration on Human Cloning (2005), Universal Declaration on Bioethics and Human Rights (2005), as well as documents of the World Health Organization, World Medical Association, Council for International Organizations of Medical Sciences (CIOMS), Committee on Ethics, Law and Society of the Human Genome (HUGO) organization.

[21] Genome Editing and Human Reproduction: Social and Ethical Issues. Published July 17, 2018. Available at: https://www.nuffieldbioethics.org/publications/genome-editing-and-human-reproduction (accessed: July 5, 2021)

Important regulatory instruments in the area of genome research and technologies include self-regulation mechanisms of the international academic community — they complement the global "soft law." They include editorial and financial policies of leading science journals and foundations (whereby articles and grant proposals should be accompanied with a confirmation of their conformity with the recommendations of international scientific organizations), opportunities for researches to participate in international collaborative projects, to have their achievements recognized by their peers, etc. Reality, however, has demonstrated the unreliability of all present instruments of global governance. The arrival of a pair of gene-edited twins in China (just several years after 2012, when the genome editing technology CRISPR/Cas9, used in the production of the twins, was created) showed one more time that technologies are an easily reproducible form of knowledge and skills.

When the huge material resources contributed by different countries and the colossal efforts made by global scientific community produced great results in the areas of DNA decoding and human genome sequencing and, finally, in creating, using all this knowledge, an effective genome editing technology (an accomplishment crowned with the Nobel Prize in chemistry in 2020), it became obvious that it would be very difficult (or maybe even impossible) to keep in check the spread and utilization of this technology in a field so dangerous as human germline editing. The Chinese experiment has met with unanimous opprobrium among geneticists and bioethicists, although the reasons for the negative reactions differ: some experts consider human germline editing unacceptable in principle while others criticize the experimenters only for taking an excessive risk and insufficiently substantiating the medical necessity of the venture. And there are nuances of opinion inside each of the two camps.

The experts who consider human germline editing acceptable include both entrenched transhumanists and those who hope that genome therapy would not be used for "improving" humans or expect that genetic engineering will be used to make humankind more humane (a prospect which, if not utopian, is very dangerous[22]). Their opponents advance two very se-

[22] In the discussions about the possibility of such "moral engineering," which by now have been going on for quite a long time in the West, some participants express concern that if humanity does not accelerate the pace of its moral improvement, it will not be able to handle the dangerous consequences of its technological power. However, as Ye. G. Grebenshchikova notes, "might it not become a beginning of the journey in which behavior and social communications will turn out to be just 'technicalities'" [Grebenshchikova Ye. G., 2016: 37].

rious arguments mentioned above. The first one: modern people have no right to make, on behalf of all future generations, such existential decisions, which can cause irreversible genetic transformations. The second argument grows from the concern that this path will lead to unmanageable social inequality both inside individual states and globally [Darnovsky M., 2008: 453]. This inequality can be of such magnitude and nature that humankind would eventually become split into different sociobiological castes.

The argument that benefits of technological progress are always enjoyed first by elites and only then by everybody else does not seem convincing: it was true in the era when elites were interested in the masses as labor or cannon fodder. It was by virtue of this interest shared by the masses and elites alike that "the great human projects of the twentieth century — overcoming famine, plague and war — aimed to safeguard a universal norm of abundance, health and peace for all people without exception. The new projects of the twenty-first century… aim at surpassing rather than safeguarding the norm, they may well result in the creation of a new superhuman caste" [Harari Yu., 2019: 103], a caste which will not be interested in raising living standards of the rest of the populace to its level. We can see how modern medicine is increasingly more preoccupied with making the rich and the healthy look younger and more beautiful, siphoning off resources from healthcare for the poor and the sick. Similar trends are emerging already in the area of genome editing: thus, three-parent fertilization method — when the damaged mitochondria in the mother's egg is substituted with healthy mitochondria from another woman's donor egg ("three-parent babies" in common parlance) — was developed for families with hereditary diseases but now is being more and more often promoted as a method for overcoming infertility induced by ageing processes [Dickenson D., 2018]. And this is just a beginning.

So, modern law, which is first of all about the rights of an individual, — will it be able to counter such a development, which can cause humanity to lose its biosocial unity, with all the disastrous social and biological consequences such a situation may entail (and perhaps for all humanity, not just for future "plebeians")?

3. Objective difficulties in addressing the problems of technological dehumanization along legal lines

The question asked should probably be answered in the negative. It is not just that national and international legislative processes are mostly controlled by political and economic elites who will use their leverage to ad-

vance their interests, that is without any concern for interests of the others. Even if the situation is to evolve within the bounds of law (by which this author does not mean abuses of power under the guise of lawfulness), one should acknowledge that law as a system of norms guaranteeing formal equality of free individuals is underpinned by a logic that is not conducive to solving universal problems of technological dehumanization. Let's consider this thesis in relation to the prospects of utilization of heritable human genome editing technologies.

Here we can clearly see how an advancement along essentially legal lines sets the stage for clinical use of human germline editing with all its dangerous consequences. Thus, according to Art.12 (1) of the International Covenant on Economic, Social and Cultural Rights (1966), each has the right "to the enjoyment of the highest attainable standard of physical and mental health," whereas the Covenant's Art.2(2) guarantees the exercise of this right "without discrimination of any kind." Similar provisions can be found, often in a more detailed form, in constitutions and laws of practically all the modern states. This means that if a person is denied the chance to give birth to a healthy child on account of the legislative ban on human germline editing, (s)he can take legal action complaining about discrimination based on the difference between his/her genetic heritage and the heritage of those who can receive somatic gene therapy (that is gene therapy not using stem cells). The share of such patients will be small because in most cases genetic disorders in fetuses can be treated with ancillary reproductive technologies, without resorting to genetic engineering; this, however, would not change anything from legal viewpoint — all individuals have equal rights (that is rights that do not depend on their genetic status) to healthcare.

So, in such situations Russian citizens may appeal to the Constitutional Court of the Russian Federation arguing that the legislation preventing them from receiving medical treatment using genome editing technologies contravenes provisions of the Constitution: Art. 41(1), guaranteeing healthcare, and Art. 19 (2), guaranteeing "the equality of rights and freedoms of man and citizen, regardless of sex, race, nationality… [and] other circumstances." If the Constitutional Court accepts the complaint, it will most likely refuse to satisfy it evoking Art.55(3) of the Constitution, whereby "the rights and freedoms of man and citizen may be limited… [when] it is necessary for the protection of" certain values of the common good. The Court, in all likelihood, would reference such value as morality (because the other values mentioned in this article obviously have no bearing on the problem at hand). But how one can prove that genome editing for medical purposes is immoral, especially when the advantages enjoyed due to the

therapy "here and now" would be greater than the risks for future generations' health? For morality is first of all humane treatment of a suffering person.

Anyway, references to the need to protect morality would not do away with the issue of discrimination in healthcare which the complainant has brought up, so his/her next step can be appealing to the European Court of Human Rights (ECHR) with a complaint about the breach of Article 14 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950), which forbids discrimination on any grounds. If, reviewing this complaint, the ECHR will bring up (as is its customary practice) the Convention of Human Rights and Biomedicine, it will have to grapple with its inconsistencies. As member of the European Group on Ethics in Science and New Technologies and former Chair of the Nuffield Council on Bioethics Prof. Jonathan Montgomery justly noted, Article 13 of the Oviedo Convention, which forbids interventions in human genome intended "to introduce any modification in the genome of any descendants," is at variance with Article 2 of the Convention, whereby "the interests and welfare of the human being shall prevail over the sole interest of society or science," with Article 3 of the Convention, which guarantees equal access to healthcare services, and with Article 11 of the Convention, which prohibits "any form of discrimination against a person on grounds of his or her genetic heritage" [Montgomery J., 2018: 39-40]. Apparently, Articles 2, 3 and 11 of the Convention, taken together, legally outweigh Article 13 and can, so to say, undo it.

As for the Convention's Article 26, which sets out criteria and reasons for restricting the use of the Convention's provisions on rights and protection, it states that "no restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as… are necessary… for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others."[23] Public health, evoked here as the common good, could hardly be interpreted as health of future generations (even in the context of the Preamble stating "that progress in biology and medicine should be used for the benefit of present and future generations").

It follows from here that remaining within a legal framework, we can find ourselves in a situation when good intentions and well-meaning ac-

[23] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo, Apr. 4, 1997.

tions will pave the way for colossal unlawful privileges of people with improved genes and, accordingly, for colossal discrimination against those without ones. Prominent German philosopher Hans Jonas in his book "The Imperative of Responsibility: In Search of Ethics for the Technological Age"[24] argued that a solution to this problem can be found along the lines of the new ethic of responsibility, which would depart from the principle of reciprocation requiring that my responsibility would mirror someone else's right. Essentially, what is suggested is that in the system of socio-normative regulation the categorical imperative of preserving humankind should take precedence over Kant's categorical imperative, which currently sets the parameters for the legal system[25]. "For me… this imperative is the only one which really fits the Kantian sense of the categorical, that is, the unconditional. Since its principle is not… the self-consistency of reason giving to itself laws of conduct… but is rather the idea of possible agents in general, for whom it claims that such ought to exist and is thus ontological, that is an idea of being — it follows that the first principle of an 'ethic of futurity' does not itself lie within ethics as a doctrine of action… but within metaphysics as a doctrine of being, of which the idea of Man is a part" [Jonas H., 2004: 62].

So, Jonas assumes that setting limits to biotechnological development — which is something he wants to achieve — cannot be solved using inner resources of the technology-driven civilization since in the final analysis these resources are always used to realize this civilization's built-in intent to conquer nature and control it through machinery. Approaching the problem from the viewpoint of metaphysics as the teaching of transcendent, ontological foundation of being, he proposes that the socio-normative system of the technology-driven civilization be guided by the doctrine "the man must exist." That said, the man, Jonas emphasizes, must not simply exist but must preserve himself in his "uncurtailed being". The categorical imperative suggested by Jonas is not a Kantian normative principle but rather a commandment, whose religious essence Jonas summarized, in the form of a question, as follows: shall we succeed in restoring the category of holiness, which was destroyed by scientific enlightenment, and again instill in the man reverence towards that "what cannot be desecrated under any circumstances" [Jonas H., 2004: 226]?

[24] In this book, published in 1979, that is long before "the era of genetics," Jonas was one of the first to contemplate possible dangers of genetic intervention in human subjects.

[25] From the viewpoint of the understanding of law on which our analysis is based, the Kantian categorical imperative expresses precisely legal, not moral, principle of formal equality [Nersesyants V.S., 2006: 623].

Sure enough, in some very distant future, when preserving people's welfare in their "uncurtailed" humanness will become impossible, people will have to go far improving that what nature gave them, if they are "to go beyond our fragile planet, as well as our fragile nature"[26]. Presently, however, embracing the ethic of responsibility, we should slow down the dangerous advancement until technological progress becomes free of existential anthropological risks. From this point of view, it appears advisable to heed the proposal of several leading geneticists and introduce a five-year moratorium on research into germline editing. An expert panel set up by the WHO in 2019 to study scientific, ethical, social and legal problems of human genome editing, however, did not endorse the idea of the moratorium (perhaps because of its unfeasibility) and only recommended "setting up a public registry for genome-editing experiments," developing standards for such experiments and setting in place mechanisms of control[27].

The realization of even this, very soft scenario of regulating the field will in large measure depend on the goodwill of the subjects of the regulation, which include national governments, national and transnational pharmaceutical companies, research collectives, sponsors of research, and individual scientists.

Because at the end of the day it is always individuals who are the carriers of will, it is important to remember that their will (first of all the will of researchers, whose personal morality theoretically could resist the pressure of governmental and commercial interests) is severely circumscribed by laws concerning state and commercial secrets. In these circumstances, one can find it very difficult to act in line with UNESCO's recommendations that states need to ensure the freedom for scientists to "express themselves freely on the human… value of certain projects and in the last resort withdraw from those projects if their conscience so dictates"[28]. So, here too law does not contribute to containing the dangerous technology trend.

As it appears, Jürgen Habermas, realizing that the technology-driven civilization's problems discussed here cannot be solved within the paradigm of legal rationality, in 2001 advanced the idea of post-secular soci-

[26] From a presentation of English philosopher John Harris at one of the forums on bioethics [Yudin B.G., 2016].

[27] Editorial. Human germline editing needs one message. Science academies and the World Health Organization must act in unison // Nature. 2019. N 575, pp. 415-416. Available at: https://www.nature.com/articles/d41586-019-03525-0 (accessed: September 29, 2021)

[28] Recommendation on the Status of Academic Researchers, UNESCO (1974). Available at: http://hrlibrary.umn.edu/instree/researchstatus.html (accessed Sept. 29, 2021)

ety (indicatively, his public lecture when he first articulated this idea took place at the time he was finishing his book "The Future of Human Nature"). The essence of the post-secular turn heralded by Habermas is "an unfair exclusion of religion from the public sphere," which "cuts off secular society from important resources of meaningfulness" which religion possesses [Habermas Yu., 2001]. However, there is yet no reason to believe that religious consciousness can become the vital spiritual resource which would help humanity to contain technological progress within safe boundaries. And one can see the unreasonable optimism of these expectations especially clearly in human genetics, where the utilization of human genome editing technologies is a competition space for different traditions of religious anthropology related to different ideas about the nature of the man and, therefore, about possibilities and limits for intervening in it.

The main stumbling block here are the question when conception occurs and the problem of the ontological or (as some would put it) legal status of the human embryo in vitro (that is an embryo outside the woman's body). The most lenient laws regulating manipulations with in vitro embryos exist in technologically developed countries dominated by Buddhism, Islam, and Judaism, and the harshest ones, in European countries with the well-established Christian traditions (Ireland, Germany, Italy, Switzerland), as well as in countries who signed the American Convention on Human Rights. In Christian cultural tradition, the embryo has the right to life from the moment of conception because this is when a person's soul is born. It is true, though, that opinions differ over the in vitro embryo: some believe that the soul is born already at the instant of insemination (and, accordingly, the in vitro embryo has the right to life as well[29]) while others argue that the conception takes place only when the embryo is implanted in the uterus[30]. In Islam, a human life begins in the 9th week after the conception, when an angel breathes soul into the embryo. And since Buddhists do not have the idea of a soul, they do not attach much importance to this question.

So, Christianity, which was once the crucial force in the formation of the technology-driven civilization, from day one had ideological checks serv-

[29] Such opinion was advanced, for instance, by Dmitry Dedov, judge from the Russian Federation at the European Court of Human Rights. See: Concurring opinion of judge Dmitry Dedov. Application no. 464470/11, Parrillo v. Italy. ECHR Judgment of Aug. 27, 2015.

[30] Artavia Murillo et al v. Costa Rica. The November 2012 decision by the Inter-American Court of Human Rights. 2020. Available at: https://www.womenslinkworldwide.org/files/462/progreso-en-la-proteccion-de-los-derechos-reproductivos-de-las-mujeres-en-latinoamerica-solo-en-ingles.pdf (accessed: April 16, 2020)

ing to curb the dangerous tendency of technologies to change the nature of human beings. Absent in the world's other religions, these checks continue to exercise considerable influence on the professional ethos of the academic community working within the sociocultural paradigm that grows from Christian worldview. It is obvious that there is little reason to hope to achieve in the foreseeable future a global moral and religious consensus over such questions, which are rooted deep in religious anthropology. Besides, nowadays the road to a consensus in this field is further hampered by the fact that the countries with softer religious prohibitions in human genome research and technologies enjoy significant advantages in global competition. Maybe in the future humanity, having got a taste of post-human reality, will find the strength to consolidate around the idea of the new ethics, which would bridle humanity's technological might.

Presently, however, one should seek solutions to the problem within legal frameworks, expanding their traditional boundaries by introducing the idea of legal responsibility towards future generations. It is noteworthy that although Jonas believed that references to the rights of future generations lie outside the legal regulation paradigm, the regulatory impact of the new categorical imperative proposed by him would be directed not so much at the metaphysical "depths of individuals' moral motivation as at public politics and [this imperative] implies shared responsibility for results of collective actions" [Gadzhikurbanova P.A., 2003: 171], and these collective actions are possible only when something like the social contract, concluded within a legal framework, is in place. It is also very telling that the attempts to reach an interfaith consensus in the declaration on global ethic ("Towards a Global Ethic: An Initial Declaration of the Parliament of the World's Religions"), proposed by Swiss theologian Hans Küng and discussed by the Parliament of the World's Religions in 1993, likewise were focused on seeking a consensus on the basis of essentially legal principles whereby: "every person [must be] treated humanely" and "we must treat others as we wish others to treat us"[31].

Working on a legal solution to the problem at hand, one can draw on the experience of global philosophy in elaborating a global environmental ethic predicated on the idea of solidarity of generations. In Russian scholarship, this experience was analyzed by A. V. Prokofiev, who identified three major theoretical models of ethic vis-à-vis future generations: contractual,

[31] Toward a Global Ethic: an Initial Declaration of the Parliament of the World's Religions. Available athttps://www.global-ethic.org/declaration-toward-a-global-ethic/ (accessed: September 29, 2021)

utilitarian, and intuitionist. As Prokofiev shows, the contractual model, the closest one to legal approach, does not work due to the already mentioned one-sidedness of intergenerational dependency. As for the utilitarian model, its sustained realization would call for excessive sacrifices on the part of present-day generations for the sake of countless descendants. According to Prokofiev, the most promising approach is the intuitivist one, whereby the rights of future generations are not based on a contract but inferred from intuitive ideas about fundamental ethical equality of people [Prokofiev A.V., 2013: 78–93].

The intuitivist approach to setting out the rights of future generations is elaborated by E.Weiss, who argues that "members of the present generation have an intergenerational right of equitable access to use and benefit from the planet's resources, which derives from the underlying equality that all generations have with each other in relation to their use of the natural system" and "each generation is thus both a trustee for the planet with obligations to care for it and a beneficiary with rights to use it"[32]. In the context of our analysis it is important to emphasize that Weiss's thesis is in line with Article 1 of the Universal Declaration on the Human Genome and Human Rights: "The human genome underlies the fundamental unity of all members of the human family… [and] is the heritage of humanity."[33] The fact that the human genome is a legacy passed on by previous generations to present generations as a single collective subject was also reflected in UNESCO's "Declaration on the Responsibility of the Present Generations Towards Future Generations," which states that the human genome "must be protected." So, the human genome is recognized is a common heritage to which present and future generations are equally entitled. Such approach arguably implies that future generations should be regarded not as a community that prevails over present generations but as a separate subject (abstract individual) with a vulnerable status and in need of additional guarantees that its interests would be taken into account in the same way as interests of other subjects of law are, on the basis of the principle of formal equality.

[32] Weiss E. Intergenerational Equity: A Legal Framework for Global Environmental Change // Environmental Change and International Law: New Challenges and Dimensions. 1992. Available at: http://www.nzdl.org/cgi-bin/library.cgi?e=d-00000-00---off-0aedl--00-0----0-10-0---0---0direct-10---4-------0-1l--11-en-50---20-about---00-0-1-00-0-0-11-1-0utfZz-8-00&cl=CL1.1&d=HASH01e262d576f8179e3bed95ea.8.3&gt=1 (accessed: Sept. 29, 2021). Quoted: [Prokofiev A.V., 2008: 247].

[33] Universal Declaration on the Human Genome and Human Rights. Available at: https://www.ohchr.org/en/professionalinterest/pages/humangenomeandhumanrights.aspx (accessed: September 29, 2021)

Another path to legal solutions for the discussed problem can be connected to the new legal construct proposed by scholars championing the introduction of responsibility for parents who agreed to have their offspring genetically modified — this legal innovation would enable "children, grandchildren and other direct kin of the subject with edited genome" to sue such parents seeking financial compensation [Trikoz Ye. N., Mustafina-Bredikhina D.M., Gulyaeva Ye. Ye., 2021: 83]. The legitimacy of this approach has been demonstrated by recent international case law, which includes legally similar suits of disabled children against doctors and parents who in the past chose not to heed the advice to terminate the pregnancy. A new legal term "wrongful life" was coined and is now used is courts [Zakharova M., Voronin M., 2018], making a moral and religious issue a legal one.

In view of the above, it should be also noted that the UN's Committee on the Rights of the Child since 2014 has the right to review complaints lodged by minors who consider themselves victims of a breach of the Convention on the Rights of the Child by a state[34], including Article 6(2) of the Convention, whereby "States Parties shall ensure to the maximum extent possible the survival and development of the child." At the present stage of affairs, for the want of better options, the prosecutor's office can use its right to initiate court proceedings to protect the right to life and health of "public at large," including into this group future generations: several Russian civil law experts propose this approach in relation to human cloning prohibition [Bogdanov Ye.Ye., Maleina M.N., Ksenofontova D.S., 2020: 134].

Conclusion

As the matters stand, there is only a slim chance that humanity will come up with an adequate answer to the challenges of technological dehumanization. The magnitude and the impact of the consequences of uncontrolled technological expansion into human nature are so great that not a single social group associated with political and economical, intellectual and spiritual elites of society can assume responsibility for decision-making in this area. And it would be all the more unacceptable to let these processes evolve at random (as largely is the case now).

A lot of international declarations, recommendations, etc. emphasize the need for an inclusive public debate about the risks posed by the newest

[34] Optional Protocol to the Convention on the Rights of the Child on a Communications Procedure. 2011. Available at: https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-11-d&chapter=4&clang=_en (accessed: September 29, 2021)

technologies and for charting future paths for technology that would be acceptable for all humankind; relevant provisions are contained in a number of international legal instruments. The realization of this advice, however, "will necessitate… hard work… and significant human and financial resources" [Andorno R. et al., 2020: 3]. Failing this, humanity will end up not with "communicative rationality" functioning within the Habermasian consensus-oriented rational discourse but with self-contradictory public opinion that will become an easy target for the manipulators owning global financial resources and pursuing their personal interests. In a situation of existential choice, the transformation of society into a real decision-maker requires new institutions for shaping and expressing society's political will. This is probably what Habermas meant writing that "in the face of a globalisation which is taking place over markets from which borders have been removed, many of us hoped for a return of the political in another form — not in the Hobbesian original form of the globalised security State, in the form of the police, secret services and now also the military, but as a civilizing, creative power worldwide. At present we have little more than the faint hope of a stratagem of reason — and a little stocktaking" [Habermas Yu., 2001].

True, one can see a glimmer of hope in the fact that the primitive man, at the very start of his journey, was able to muster his inner resources of reason and will power needed for curbing his destructive animal instincts through social creativity. So the modern man, too, may prove to be able to stop at the threshold of post-human future or walk into the new era without losing his humanity. Given these prospects for the foreseeable future, in the realm of philosophy of law, the ideas of Russian religious philosophers about all-encompassing unity, with its "anticipation of a disaster for all and the idea of salvation for all" [Gulyga A.V., 2004: 22], become especially relevant and acquire a new meaning.

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Prospects of Legal Regulating Use of Driverless Transportation Vehicles in the Russian Federation

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Abstract

The article reviews the new Russian legislation introducing the experimental legal regime for the use of highly automated transportation vehicles (HATVs) (driverless vehicles) on public roads. The article analyzes strategic planning documents related to the subject, such as the governmental Traffic Safety Concept for Public Roads with Driverless Transportation Vehicles (DTVs) and the European Union's documents regulating the use of robots and artificial intelligence (AI). Drafts of the relevant laws presently at the stage of public debate or discussion at the Duma are reviewed. The Russian experience of legal regulation is compared to the international experience, with conclusions made about possible directions for the development of the legislation. The article broaches the issues of apportioning tort and administrative liability for damage caused by the use of HATVs or as a result of a breach of the road rules by such vehicles. The obvious hurdles in the way of imposing liability on a robot or an AI algorithm underscore the need to hold on to the classic tort liability model adjudicating claims of damage caused by hazardous objects and modify this model to make is usable for situations when damage is caused by a DTV. In a separate section, this article addresses issues related to the use of delivery robots — the objects do not fit the definition of transportation vehicles provided in the road rules and in the drafts of legal acts currently being prepared. The conclusion is made that judicial opinions should provide clarifications for accidents involving such vehicles because, moving along sidewalks and crossing traffic areas, they are actually road users. As for risks for personal rights and freedoms associated with the use of DTVs, this writer focuses on risks related to the collection and use of passengers' personal data, as well as risks of mass layoffs arising from the probable decline in demand

for taxi and truck drivers and street traffic controllers. Relying on the results of the analysis, this author suggests how to proceed with the legal regulation of the use of HATVs and reflects on legal and socio-economic implications of their large-scale use in Russia.

Keywords

theory of law, information law, artificial intelligence, robotics, driverless vehicles, robotic vehicles, digitization, experimental legal regimes, regulatory sandbox, information security.

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Introduction

In recent years our country has seen great technological advancements in designing and developing a new generation of transportation vehicles, which can drive autonomously, without direct human inputs. The research and development of the new technologies is currently focused on several areas: development of driver assistance technologies and analogs of "autopilot" in production vehicles; creating, on the basis of these systems, experimental DTV models and designing so-called "intelligent roads" compatible with the new types of vehicles that drive taking cues from digital markers and notifications. As for the Russian market, which, according to analysts[1], is bound to experience a boom as soon as the nearest decade, its leaders include Yandex SDC, SberAutoTech, and KamAZ.

The Covid-19 pandemic — or, rather, the associated risks and anti-pandemic restrictions — is also likely to contribute to the development of driverless vehicles. Driverless taxis, whose passengers do not have to come into contact with drivers, and driverless deliveries of purchased goods, whereby couriers does not get in touch with sellers and buyers, are obviously much safer options than the alternatives, given the persistent dangers to people's life and health. One would assume that consumers will keep a positive attitude to these technologies even after the lifting of the COVID-related restrictions because the models of social behavior shaped by the pandemic

[1] See, for instance: Yandex's Unmanned Vehicles Business Worth $7 Billion: Estimate. Forbes, Aug.5, 2021. Available at: URL: https://forbes.ru/tehnologii/436537-bespilotnyy-biznes-yandeksa-ocenili-v-7-mlrd (accessed: Oct. 1, 2021)

cannot disappear in an instant. Besides, according to economists' estimate, a large-scale use of driverless deliveries can produce positive economic effects due to dramatic cuts in transportation costs caused by fuel savings [Lazutkina V.V., Pokusaev O.N. et al., 2018: 66–80], is expected to contributed to a decline in the numbers of road traffic accidents [Shaklein A.G., Pokusaev O.N. et al., 2019: 104–114] and, as a result, may reduce the final costs of goods and services.

In 2016 this writer attempted to outline main problems related to the absence (then) of legal regulation of the use of DTVs in our country. In particular, this writer highlighted three key clusters of legal issues:

absence of a legal definition and classification of driverless vehicles;

absence of a legal framework for granting DTVs access to public roads (state registration of DTVs is impossible, the issues of compatibility of the national and supranational regulatory frameworks, etc.);

mootness of the issues of assigning liability for damage caused by the use of a DTV.

And referencing countries that attempt to "legalize" the use of DTVs, this writer, in his 2016 study, mentioned the USA and Asian countries, which carry out experiments in legal regulation of the field in specially designated regions. Thus, in the USA DTVs may be used mostly in small towns in several American southern states, and in Michigan such vehicles do not even need to have an engineer in the driver's seat. At the same time, researchers point out that the American lawmakers have to tackle the problem of apportioning liability for road traffic accidents involving DTVs, which slows down the process of DTVs-related lawmaking [Voronin D.A., Makarevich M.L., 2018: 126].

The countries such as the USA, China, Singapore and Japan enjoy a greater freedom in the matters of legal regulation of road traffic since they are not signatories of the 1968 Vienna Convention on Road Traffic[2], which the Russian Federation (Russia) have joined in 1993. "The stumbling block" for the convention's signatories is its provisions whereby "every moving vehicle or combination of vehicles shall have a driver" (Art. 8 (1), who "shall possess the necessary physical and mental ability and be in a fit physical and mental condition to drive" (Art. 8 (3) and who "shall at all times be able to control his vehicle" (Art.8 (5). A literary interpretation of the Vienna

[2] The Convention on Road Traffic (adopted in Vienna Nov. 8, 1968, amended Sept. 23, 2014). Available at: https://unece.org/fileadmin/DAM/trans/conventn/Conv_road_traffic_EN.pdf (accessed: Oct. 1, 2021)

convention's thesaurus suggests that the document rules out the possibility of a self-driving vehicle without a human in the driver's seat — in any case, vehicles without drivers most certainly were simply not a feasible option to consider at the time when the convention was adopted.

In 2014, at its 68th session, the Working Party on Road Traffic Safety of UN's Inland Transport Committee has adopted amendments to the Convention initiated by several European countries and complementing Art.8 with clause 5-bis, "legalizing" the use of autonomous control systems for transportation vehicles. These amendments were published on September 23, 2014, and came into force, for the Russia and the Convention's other signatories, on March 23, 2016. Analyzing these amendments, legal scholar A.V. Neznamov remarked that one of the necessary conditions for using such autonomous systems was the presence of the option of switching them off, which the driver could avail himself of at any moment, so claiming that we witness a full "legalization of completely autonomous vehicles is a little too soon" [Neznamov A.V., 2018: 178].

It can be argued, however, that a more liberal approach to interpreting these provisions of the Convention is possible since the document does not directly require that the driver with the necessary psychological and physical qualities be seated inside the vehicle. This writer believes that the Convention's version presently in force implicitly provides that the operator can be situated in a DTVs control center. In line with the amendments adopted in 2014, this operator is capable of switching off the automated system and assuming the responsibility for driving the vehicle in a situation when the vehicle is "confused." A case in point is a situation when a DTV driving along a single-lane road encounters the scene of a road accident and, due to the presence of road surface markings, cannot bypass this site. Under such circumstances, the operator can examine videos from the DTV's external surveillance cameras and, making sure that crossing into an oncoming lane would be safe, give the vehicle a one-time permission to do so.

If such an interpretation is to be adopted, it can be assumed that the legalization of the use of DTVs in our country presently would not require amendments to the international legislation and can be effected at a national level. Moreover, Russian lawmakers already took first steps in this direction.

1. Legislative innovations

In 2018 the public authorities set about addressing the issues mentioned above, following in the American footsteps to some extent in terms of regu-

lation. In its Order No.1415 the Russian government introduced Regulations Concerning the Pilot Project of Using Highly Automated Transportation Vehicles (HATVs) on Public Roads[3](hereinafter referred to as the Regulations), whereby the experiment is to run between December 1, 2018, and March 1, 2022, in Moscow and the Republic of Tatarstan. This writer concurs with legal scholar A. V. Neznamov, who pointed out that these two regions are probably unlikely to provide sufficient data for the nationwide introduction of HATVs because roads in these regions are superior to those that can be found elsewhere in Russia whereas the selected regions themselves are more or less similar in terms of climate and topography (Komarov S.V., Stolbova N.V., Neznamov A.V. et al., 2019: 60].

In March 2020 other regions joined the experiment: Vladimirskaya, Leningradskaya, Moskovskaya, Nizhegorodskaya, Novgorodskaya and Samarskaya Oblasts (provinces), Republic of Chuvashia, Khanty-Mansi and Yamalo-Nenets Autonomous Okrugs (autonomous areas), Krasnodarsky Krai (region), and Saint Petersburg. The addition of new Russian regions to the list of the experiment's participants is an evidence of a great economic attractiveness of the new technologies since the mentioned regions, leaders of the national economy, are regarded as attractive by investors. Besides, such expansion testifies to a certain level of HATVs' safety, proven during the first years of the experiment. As this writer's has learned monitoring the news, perhaps the only road accident for which an HATV was "responsible" took place in Moscow in 2019, caused by the driving engineer's error. In the other known cases of road accidents involving HATVs, drivers of ordinary vehicles were the responsible party.

The Regulations were provided with a legal foundation *post factum*, with the adoption of Federal Law No. 258-FZ (July 31, 2020) On Digital Innovation Experimental Legal Regimes in the Russian Federation[4]. Although this law was adopted one year and a half, and came into force two years, after the experiment's start, its Art. 2(2), referencing main directions of the

[3] Order No. 1415 of the Russian Federation Government. Nov. 26, 2018. On the Pilot Project of Using Highly Automated Transportation Vehicles on Public Roads [O provedenii eksperimenta po opytnoy ekspluatatsii na avtomobil'nykh dorogakh obshchego pol'zovaniya vysokoavtomatizirovannykh transportnykh sredstv] (as amended on Febr. 22, 2020). Compendium of Laws of the Russian Federation [Sobranie zakonodatel'stva Rossiyskoy Federatsii]. Dec. 3, 2018. No. 49 (part VI), Art. 7619.

[4] Federal law No. 258-FZ July 31, 2020, as amended July 2, 2021 "On Experimental Legal Regimes in the Area of Digital Innovation in the Russian Federation" [Ob eksperimental'nykh pravovykh rezhimakh v sfere tsifrovykh innovatsiy v Rossiyskoy Federatsii]. Available at: URL: www.pravo.gov.ru (accessed: Oct. 1, 2021)

experimental legal regimes, mentions design, manufacturing and using transportation vehicles, including HATVs and driverless aerial vehicles.

It needs to be mentioned that from the constitutional point of view the idea of introducing experimental legal regimes may appear questionable. If we posit that: the utilization of HATVs in any given region of the Russia increases the chances of road accidents for this region's residents in comparison to residents of non-participating regions, and residents of such designated region who do not wish to participate in the legal experiment essentially have no choice, then it would be safe to conclude that the introduction of the experimental legal regimes is at variance with the general legal principle of equality and non-discrimination[5]. As a possible counterargument to the above statement, one can say that the AI systems responsible for HATVs are much more "disciplined" than the average driver, whereas AI's level of concentration on driving is likewise much greater since driving is the only thing on which HATVs' operation systems can focus their attention. One would assume that a definitive answer to this question should be given by the Russian Federation's Constitutional Court, if the constitutionality of the mentioned federal law is questioned.

As legal scholar V. O. Makarov notes, the model of experimental legal regimes ("regulatory sandboxes") is not something unique to our country as it is widely used internationally. Under this model, the state temporarily exempts companies developing new technologies from existing regulations in order to test the hypothesis that outdated legal norms should be abolished [Makarov V.O., 2020: 18–24]. Such approach, in our opinion, is more prudent than legislating "by intuition," relaying on lawmakers' ideas of what is good and what is bad. One would assume that when the regional experiments on the use of HATVs are over, the next necessary step to take would be to consider introducing relevant amendments to the federal legislation.

2. Issues of terminology

According to the Regulations, an HATV is a transportation vehicle released in the Eurasian Economic Union and authorized for use as a transportation vehicle in the Russian Federation, whose factory-made equipment has been complemented with an automated driving system and whose

[5] Article 19 of the Constitution of the Russian Federation. Adopted by national referendum on Dec.12, 1993, as amended by national referendum on July 1, 2020. Available at: URL: www.pravo.gov.ru (accessed: Sept. 1, 2021)

ownership cannot be transferred to any other party while the experiment is underway. We are talking here not about half-baked products at the stage of development which have not been certified, tested for safety and undergone other necessary procedures, but about transportation vehicles which, while not yet common in the stream of commerce, have been certified as fit for use and re-designed to become autonomous. At the experimental stage, owners of HATVs may not enter into transactions transferring ownership rights to their vehicles to any third parties.

It should be noted that the Society of Automotive Engineers (SAE) International developed "a taxonomy with detailed definitions for six levels of driving automation"[6]:

level 0 — a vehicle entirely operated and controlled by a human being ("No Driving Automation");

level 1 — human-operated vehicle is equipped with basic automation features (for instance, cruise control and road markings compliance) ("Driver Assistance");

level 2, when a vehicle can drive a certain distance in a real road environment in autopilot mode (this technology is known as adaptive cruise control) ("Partial Driving Automation");

level 3, when a vehicle can autonomously overtake other vehicles and safely exit a road ("Conditional Driving Automation");

level 4, when a vehicle drives autonomously and chooses a route, but in difficult situations (a road accident or a strong deterioration of the weather) the vehicle operation is taken over by a human driver ("High Driving Automation");

level 5, a fully autonomous (driverless) vehicle [for more information about this, see [Shadrin S.S., Ivanova A.A., 2019] ("Full Driving Automation").

This taxonomy is important as a guidance for various models of apportioning tort liability because even a partial discharge from this liability can be granted to the driver only in case of the 4th or 5th levels of automation. As for possible accidents related to failures of the "driver's assistants" in ve-

[6] Society of Automotive Engineers (SAE) International, standard J3016_202104. Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles. (revised on April 30, 2021). Available at: https://sae.org/standards/content/j3016_202104 (accessed: Oct.1, 2021). The Russian text of this article contains the translation of excerpts from the Standards accomplished by the article's author.

Illustration 1. 4th-level HATV

Source: Yandex's corporate blog.

hicles with lower automation levels, this writer believes that they are hardly much different from the situations involving technical failures in 0-level automobiles, which may be caused by manufacturing defects, poor maintenance, the driver's lack of judgment or other factors. Some of these causal factors — for instance, a failure of the stability control due to a defective part in the automobile's brake gear — can warrant the vehicle's owner's filing of a lawsuit against the car maker or the part provider.

The Regulations do not specify the levels of automation implied, although if we systemically interpret the thesaurus in §3 of the Regulations, it would be fair to assume that the reference is made to the levels 4 and 5. The Regulations' requirement that the driver be present in the HATV's driver's seat at all times appears to be of a provisional nature, suitable perhaps to the 3rd automation level, and, one would think, should be omitted from later legal acts, during final stages of the regulatory experiment. Perhaps, as an interim measure, lawmakers could adopt a requirement that the engineer be present in the HATV's passenger compartment but not necessarily in the driver's seat. In the global practice of HATV testing, this level of autonomous driving is usually graded as 4, whereas level 5 refers to a total absence of the engineer in the passenger compartment.

The Concept of Ensuring Traffic Safety on Public Roads with Driverless Transportation Vehicles (hereinafter referred to as the Concept), adopted

by the Russian Federation Government in 2020, uses, along with the term HATV, the term "fully automated transportation vehicle" (hereinafter referred to as FATV), describing it as the level 5 vehicle[7]. The Concept also uses the blanket term "driverless transportation vehicle" (DTV), which refers both to HATVs and FATVs; moreover, it has an annex with a table of five levels of autonomous driving in keeping with the SAE International's standards (save level 0).

The issue of terminology in legal regulation of DTVs appears to be important for two reasons. Firstly, definitions introduced in legal acts should be harmonized with administrative law, insurance- and transportation-related legislation, and road rules. Secondly, Russian legislative innovations should be in keeping, or at the very least not be directly at odds, with supranational regulatory documents, including non-binding ones, related to the use of HATVs. Thus, in the absence of a special general European act on the use of HATVs, some of the relevant issues are addressed in the European Parliament's resolution of 2017 on civil law rules on robotics[8], the European Commission's 2020 recommendations on regulating AI[9], and some other acts. These acts extensively address the questions of ensuring information safety in the process of creating relevant software because it is precisely defects of the software that arguably pose the greatest risks for HATVs. The documents also address the software producers' obligation to take reasonable and sufficient measures to prevent unauthorized interference (hacking) of HATVs.

The issues of compensation for damage in case of traffic accidents involving ordinary vehicles that take place in the EU are regulated by national legislations of the member states, although if the EU authorities continue

[7] Instruction No. 724-p of the Russian Federation Government (March 25, 2020). On the Concept of Ensuring Traffic Safety on Public Roads with Driverless Transportation Vehicles [O Kontseptsii obespecheniya bezopasnosti dorozhnogo dvizheniya s uchastiem bespilotnykh transportnykh sredstv na dorogakh obshchego pol'zovaniya]. Compendium of Laws of the Russian Federation [Sobranie zakonodatel'stva Rossiyskoy Federatsii]. March 30, 2020. No. 13, Art.1995.

[8] European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2013(INL). Available at: https://europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.html (accessed: Oct.1, 2021). The Russian text of this article contains a Russian translation of excerpts from the resolution accomplished by the article's author.

[9] European Commission. White Paper on Artificial Intelligence — a European approach to excellence and trust. Com(2020) 65 final. Available at: https://ec.europa.eu/info/sites/default/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf (accessed: Oct.1, 2021). The Russian text of the article contains a Russian translation of excerpts from the paper accomplished by the article's author.

to discuss the use of HATVs, the debates can quite possibly lead to the adoption of supranational legal acts in this area as well. The EU lawmakers' efforts to unify national legislations should be taken notice of by their Russian counterparts because presently there hardly exist any objective reasons to ignore the legislative processes in Europe while developing Russian pieces of legislation.

Also noteworthy is the draft of the federal law "On Innovative Transportation Vehicles and on Introducing Amendments to Certain Legal Acts of the Russian Federation" (draft law no. 910152-7)[10], which was submitted, in 2020, to the Duma by the State Council of the Republic of Tatarstan and which was rejected by the Duma on formal grounds (because the government did not produce an official budget estimate for the law). In the thesaurus of the draft law, the authors of the draft proposed such definitions as an "innovative transportation vehicle," an HATV, and an DTV, with a special legal regulatory framework for each of the three. The innovative transportation vehicle was defined as any transportation vehicle with new structural features (not necessarily related to automated control), and the definitions of HATVs and DTVs essentially corresponded with the 4th and 5th levels of autonomous driving from SAE International's Standards. This writer believes that the presence of different legislative frameworks for HATVs and FATVs can be useful for addressing issues associated with the imposition of tort liability.

Yet another noteworthy draft of a federal law, "On Highly Automated Transportation Vehicles and on Introducing Amendments to Certain Legal Acts of the RF," was published online in June 2021 on the federal portal where legislative proposals are posted for public consideration[11]. Prepared by Russia's ministry of transportation in cooperation with Yandex SDC and SberAutoTech[12], this draft is a logical continuation of the legal experiment

[10] A draft of the federal law On Innovative Transportation Vehicles and on Introducing Amendments to Some Legal Acts of the Russian Federation [Ob innovatsionnykh transportnykh sredstvakh i o vnesenii izmeneniy v otdel'nye zakonodatel'nye akty Rossiyskoy Federatsii]. Available at: URL: https://sozd.duma.gov.ru/bill/910152-7 (accessed: Oct. 1, 2021)

[11] A draft of the federal law "On Highly Automated Transportation Vehicles and on Introducing Amendments to Some Legal Acts of the Russian Federation" [O vysokoavtomatizirovannykh transportnykh sredstvakh i o vnesenii izmeneniy v otdel'nye zakonodatel'nye akty Rossiyskoy Federatsii]. ID of the draft: 02/04/06-21/00116763. Available at: URL: https://regulation.gov.ru (accessed: Oct. 1, 2021)

[12] See, for instance: A Law for Driverless Vehicles [Bespilotnym avto zakon pisan]. Kommersant, June 11, 2021. Available at: URL: https://kommersant.ru/doc/4856110 (accessed: Oct.1, 2021)

in the use of HATVs on public roads. The key feature of the draft is a provision for operating an HATV without an engineer in the driver's seat — the usefulness of this provision has been discussed above. Art.1 of the draft law contains a detailed thesaurus without, however, differentiating between types of DTVs depending on their level of autonomous driving. In addition to establishing obligations of possessors, operators and manufacturers of HATVs, the draft also provides for amendments to the transportation- and insurance-related legal frameworks, which presently often do not distinguish between ordinary transportation vehicles and HATVs. Moreover, Art. 3 of the draft prioritizes the Russian Federation's international agreements on the use of HATVs, which include the Vienna Convention and — if a broad interpretation is applied — the mentioned recommendations of the EU.

The ministry of transportation's draft law is in line with the government's Concept and appears to be a very timely document. This writer wants to highlight that the draft, in Art.17, defers the law's coming into force until March 1, 2025. The draft's authors, as it seems, expect to use the interim period for elaborating and introducing necessary amendments to the road rules and other acts. Besides, as the period designated for the legal experiment is drawing to a close, Russia's Ministry of Economic Development has produced and published on the federal portal of drafts of legal acts a draft of the governmental Order introducing yet another legal experiment in the use of HATVs[13], to run for 3 years. The thesaurus provided in the draft identifies "1st category HATVs," which have a test driver in the driver's seat, and "2nd category HATVs," with remote-control routing and operation. So, this legal experiment will probably replace the current one and last from 2022 to 2024.

3. Liability issues

This writer agrees with renowned legal scholar V. B. Naumov in that an overproduction of legal acts related to high technologies can result in a lack of legal certainty, when lawmakers, generating reams of norms while ignoring the rules of legislative drafting, create a new disorder instead of bringing order to legal relations [Naumov V.B., Butrimovich Ya. V. et al., 2020: 40–49]. Creating a separate body of law to address violations of the

[13] A draft of the Order of the Government of the Russian Federation "On Introducing the Digital Innovation Experimental Legal Regime and Approving the Use of Highly Automated Transportation Vehicles Programs in Conjunction with this Regime" [Ob ustanovlenii eksperimental'nogo pravovogo rezhima v sfere tsifrovykh innovatsiy i utverzhdenii programm eksperimental'nogo pravovogo rezhima v sfere tsifrovykh innovatsiy po ekspluatatsii vysokoavtomatizirovannykh transportnykh sredstv]. ID of draft: 01/01/09-21/00119869. Available at: URL: https://regulation.gov.ru (accessed: Oct.1, 2021)

road rules by HATVs is unlikely to contribute to traffic safety if these norms cardinally differ from the norms applicable to ordinary transportation vehicles. Such norms should be based, as much as possible, on rules and institutions familiar to drivers, otherwise road users are bound to have hard time assimilating these rules. In this context, road traffic regulation can be called one of the most conservative fields because basic road rules practically have not changed since the time of the first traffic lights and road signs.

In this context, one is reminded of the news of the late 19th — early 20th centuries, when the first road accidents involving steam-driven "self-moving carriages" were recorded in London, New York, Paris and other big cities. These news items fairly often contained demands to prohibit the use of the vehicles on account of their very high and dangerous speed, which, in case of the most advanced "self-moving carriages," could be as high as 10-12 km/hour.

In 1861, not without the "help" of the railroad lobby, fearful of losing some of its revenue to producers and operators of steam-driven automobiles, the UK Parliament passed the Locomotive Act[14], restricting speed for all steam-driven locomotives (which then included automobiles as well) to 10 miles an hour in out-of-town areas and 5 miles an hour in "any City, Town, or Village." Amendments introduced to this law in 1865 reduced the maximum speed to 4 miles an hour out of town and 2 miles an hour in cities, towns and villages; another new provision required that every "steam-driven locomotive" in a city should be accompanied with a man, walking in front of it and carrying a red flag high in his hands, warning pedestrians about the danger; the law was called accordingly — Red Flag Act[15]. These restrictions, reasonable for railroad vehicles but absolutely absurd for automobiles, were lifted only in 1896, when the new Locomotive Act exempted locomotives weighing less than 3 tons from this requirement.

The attempt to place on the same footing a new, unregulated type of transportation vehicles and railroad, a kind of transport well familiar to the public by then, resulted in a period of serious stagnation for British car making industry. In the early 20th century British automotive engineers had to copy works of their German and French colleagues because in Germany and France such restrictions were not imposed, despite the pressure of

[14] Locomotive Act, 1861. Available at: URL: https://legislation.gov.uk/ukpga/Vict/24-25/70/enacted (accessed: Oct. 1, 2021)

[15] An Act for further regulating the Use of Locomotives on Turnpike and other Roads for Agricultural and other Purposes, 1865. Available at: URL: https://archive.org/details/statutesunitedk30britgoog/page/n247 (accessed: Oct. 1, 2021)

public opinion and lobbying groups. So, British lawmakers' essentially proscriptive policies in relation to first automobiles caused an entire industry to lag far behind similar industries in other countries. One hundred years later, we cannot imagine modern life without cars, and economy, without automotive freight.

Lawmakers nowadays face a largely similar dilemma: to allow the use of HATVs or to artificially retard the sector's development citing as an excuse these vehicles' insufficient safety. If the second alternative is adopted, in the foreseeable future we are certain to need large-volume purchases of driverless vehicles and relevant software from international providers. The choice is difficult, however, because it is impossible to weigh technological progress against hypothetic human casualties which may result from a total absence of restrictions on the use of HATVs. Given this, the key question of legal regulation in the field under review appears to be the question of apportioning liability in road accidents involving HATVs.

Thus, renowned legal scholars N. V. Rumyantsev and V. V. Zhuravlev argue the presumption of the vehicle owner's guilt, which the administrative legislation automatically applies in the cases of (video)recorded administrative violations, can be equally applied to owners of HATVs [Rumyantsev N.V., Zhuravlev V.V., 2020: 196–200]. This writer agrees with the approach whereby in cases of speed violations, or violations of the rules regulating the use of a vehicle's lighting devices, by an HATV the vehicle's owner will have to prove in court that (s)he is not a guilty party.

This approach appears to underpin §18 of the mentioned Regulations, as well as the ministry of transportation's draft law, whereby the HATV's owner is responsible for traffic accidents and other accidents on the RF's motor roads involving his/her HATV, in the absence of wrongdoing on the part of other road users that resulted in the accident. The category of other road users should arguably include not only pedestrians and drivers of other vehicles, but also passengers of HATVs utilized by their owners as taxis. Passengers of HATVs will be fully responsible for their wrongful acts, such as, for instance, an attempt to damage the HATV or throwing garbage from a window of the moving HATV. In relation to such passengers the HATV's owner will probably apply additional disciplinary measures such as blocking their accounts and banning the passengers from using the carrier's services in future. So, adjudicating a hypothetical violation of traffic rules by an HATV or a compensation claim arising from a traffic accident involving an HATV, the court will have to assess whether — and if so, to what degree — a person in the driver's seat could regulate the character and

speed of the HATV's movement. So owners of HATVs should be interested in reducing the probability of such occurrences to zero.

Presently it seems safe to say that Russian companies participating in the legal experiment in the use of HATVs behave themselves very responsibly. A proof of this is the fact that they buy HATV civil liability insurance policies that are several-fold more expensive than the maximum coverage for insurance policies of ordinary vehicles' drivers (up to 10 million rubles against 400,000 rubles of the maximum coverage for mandatory motor insurance). One would think that during the legal experiment owners of "freight" HATVs, too, would be insuring their cargoes for bigger sums than their sector's average.

At the same time, legal scholars A. I. Chuchaev and S. V. Malikov note that when a person in an HATV's driver's seat is treated the same as the driver of an ordinary vehicle, this person is thus assigned a greater responsibility than the HATV's owner because it is the driver's obligation to ensure that the road rules are observed and to prevent traffic accidents. HATVs' owners, in legal scholars' opinion, should rather be held liable for software-hardware failures that cannot be remedied by drivers [Chuchaev A.I., Malikov S.V., 2019: 117–124]. Besides, nowadays in continental systems of justice, in case of injuries or fatalities resulting from traffic accidents, it is precisely the driver, as an individual, and not the HATV's owner (usually corporate owners) or, much less, artificial intelligence, who would be held criminally liable [Kamalova G.G., 2020: 382–388]. Apparently, when HATVs no longer have drivers in driver's seats (and perhaps when even the idea of "the driver's seat" becomes obsolete), this problem is bound to re-emerge.

European legal researchers in general argue that strict liability should be imposed on HATVs' owners [Engelhard E., de Bruin R., 2018], by analogy with hazardous objects, a category well known to Russian/Soviet legal scholars [Antinomov B.S., 1952]; [Fleishits E.A., 1951, etc.]. Such approach appears justified because the share of road accidents caused by drivers' lack of attention or inadequate state of mind (alcoholic intoxication, overfatigue, etc.) will steadily decline as the share of DTVs on public roads will grow. According to the U.S. National Highway Traffic Safety Administration, which every years analyzes data on more than two million road accidents involving ordinary vehicles, "the critical reason" in 94% of the accidents is attributed to drivers' errors or non-performance[16].

[16] Critical reasons for crashes investigated in the national motor vehicle crash causation survey. NHTSA, 2018. Available at: https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/812506 (accessed: Oct.1, 2021)

4. Ethical and legal issues

The issues of criminal liability in the event of injury or fatality caused by an HATV inevitably touch on ethical issues. The largest carmakers claim that the autopilot systems installed in production vehicles of the 2nd and 3rd automated driving levels are as safe as can be and programmed to strictly comply with speed limits and road markings. And yet, speaking about programming, such systems should provide for a choice in emergency situations — for instance, a choice between hitting a pedestrian and hitting an obstruction when emergency braking is insufficient. 4th- and 5th-automated driving level HATVs can get into such situation as well, and in case with the 5th-level HATV the person in the passenger compartment will not even be able to intervene with the controlling algorithm. The probability of such scenario is close, although not equal, to zero, so it should be reflected in the software. Several years ago quite a stir was created when a major German carmaker declared that their autopilot systems in such situations would prioritize lives of the driver and the passengers[17]. For all the seeming inhumaneness of this approach, the carmaker's logic is understandable: there are hardly many buyers for a driverless vehicle which, in case of an emergency, is bound to sacrifice its occupants' life and health.

This problem is a present-day version of the well-known ethical-philosophical dilemma called "the trolley problem": a person has to choose (or evaluate other person's choice) between inaction which is bound to kill several people and an action bound to kill one person but save the rest. The most famous version of this dilemma is the fat man dilemma: when a trolley, racing along a track, is going to run over 5 people in front of it, and to stop the trolley, one has to throw an overweight person on the track. An adaptation of this dilemma to the HATV realities can look like this:

a child crosses the road outside the designated crossing area, getting in the way of an HATV, whose speed and short distance from the child made it impossible to stop without hitting the child;

a child does not see an HATV moving towards him/her nor can (s)he run off to escape the vehicle;

there are no people around who can intervene and save the child;

[17] See, for instance: Self-Driving Mercedes-Benzes Will Prioritize Occupant Safety over Pedestrians //Car & Driver, Oct.7, 2016. Available at: https://www.caranddriver.com/news/a15344706/self-driving-mercedes-will-prioritize-occupant-safety-over-pedestrians/ (accessed: Oct.1, 2021)

on the sidewalk, there is an old man — he, too, does not see the HATV and the child, but if the HATV moves aside, it would inevitably run over this man.

To simplify the model, let's add that the HATV does not have any third option because the sidewalk is narrow or because the oncoming lane has vehicles speeding along. The HATV, meanwhile, is sufficiently "intelligent" to understand that the child and the old man cannot avoid the collision but it cannot assess in advance the seriousness of the injuries the pedestrians and the HATV's occupants would suffer as the result of the clash.

Attempting to solve the trolley problem in relation to driverless vehicles, professor A. Wolkenstein from Institute of Ethics, History and Theory of Medicine in Munich concludes that this dilemma should not be applied to regulation of driverless vehicles at all. In his opinion, the moral logic underpinning the trolley dilemma is inapplicable to AI systems, which are constitutionally indifferent to death and, so, cannot make moral choices in principle. Second, whereas participants of the ethical experiments are informed about precise consequences of their decisions, HATVs, let alone developers of their software, can only make guesses about possible consequences of such acts. The numerous experiments in moral psychology, therefore, can hardly be useful for programming HATVs or legislating their operation [Wolkenstein A., 2018: 165, 168]. At the same time, in this writer's opinion, applying even a refined version of the trolley dilemma to HATVs, we can make a significant contribution to the discussion of the ethics of AI's algorithms.

5. The highest level of autonomous driving

Nowadays streets of Moscow and Innopolis are plied by delivery robots which are not designed to have a driver. This is so-called rovers, which in the foreseeable future can have a serious impact on the market of delivery services, gradually substituting delivery boys and girls. These rovers do not fit into the road rules' definition of a transportation vehicle or the definition of an HATV in the Regulations and the Concept. Similarly, they hardly fit into the other categories of transportation vehicles referenced in the road rules, such as kick scooters or bicycles, because they are not meant for transportation of people. At the same time, *de facto* the rovers are road users who ply sidewalks and cross traffic areas, while their software is programmed to comply with the road rules. The users' operational capabilities vis-à-vis the rovers are limited to providing delivery addresses and confirming the delivery receipt, so it will be the delivery robot's owner who will be held liable for harm caused by the machine.

Illustration 2. Yandex Rover Delivery Robot.

Source: corporate blog of Yandex.

That said, in reality, however, more often than not the rovers become "the injured party": not only pedestrians vandalize them pedestrians but car drivers, likewise, quite often hit them in pedestrian crossing areas, at entries to courtyards, on parking lots or on sidewalks. It seems doubtful that such situations should be categorized as a collision between a vehicle and a pedestrian (in the absence of the latter); and yet, they may not only result in a civil lawsuit but also be classified as an administrative offence — for instance, if the car drove on the sidewalk in violation of the road rules. At the present stage of the rovers' technological development, their use hardly requires significant amendments to the legislation, although some issues related to the application of law need to be addressed in judicial opinions. This judicial practice, in turn, can produce legal positions applicable to the regulation of FATVs.

This writer wants to point out an important clarification from court rulings related to the importance of the term "possessor," referenced in Art.1079 of the RF's Civil Code[18]: "possessor" means an owner of the transportation vehicle or its lawful possessor (someone who controls, manages

[18] Civil Code of the Russian Federation (part 2) (Jan.26, 1996), No. 14-FZ (as amended on March 9 and July 8, 2021). Compendium of Laws of the Russian Federation [Sobranie zakonodatel'stva Rossiyskoy Federatsii], Jan.29, 1996, no. 5, p. 410.

or otherwise handles the vehicle in any of the numerous other capacities)[19]. The mentioned draft law prepared by the ministry of transportation is based on this notional framework, although attempts to apply this framework to FATV-related tort liabilities brings out a fundamental contradiction: when someone is authorized to manage a FATV by a power of attorney but has no controlling organs at all — can we consider such person the possessor of a hazardous object?

In the foreseeable future, the following hypothetical circumstances can complicate the tort collisions:

a big carmaker buys from third-party producers hardware and software to install in its cars in order to achieve a certain level of autonomous driving capabilities, and these installations break down;

an ordinary automobile's owner himself buys hardware, turning his/her car into a driverless vehicle, and the improperly installed hardware fails;

a DTV's owner does not follow the manufacturer's recommendations — for instance, does not update the software, and the equipment breaks down as a result;

the "intelligent road" infrastructure breaks down and a DTV, in response to an incorrect data feed, suffers a traffic accident;

a technical failure causes damage to an HATV's owner who is in the driver's seat — and only to him (for instance, during an idle interval the airbag unnecessarily deploys);

third parties "hack" the software of one or several DTVs, causing traffic accidents with their involvement.

This is far from being a full list of the challenging situations which lawmakers and courts will have to address in the nearest future. Some of the concepts developed for modern FATVs — such as SberAutoTech's Flip, for instance — are much closer to driverless public transport than to personal vehicles because all of the vehicle's occupants are in fact passengers. Here Russian lawmakers could take a leaf from international legal models of passenger transportation in driverless public vehicles — for instance, in Dubai's driverless metro.

[19] §§18, 19 of Ruling No. 1, Plenum of the Supreme Court of the Russian Federation. Jan. 26, 2010. On Application by the Courts of the Civil Law Regulating Liability Resulting from Fatalities or Injuries [O primenenii sudami grazhdanskogo zakonodatel'stva, reguliruyushchego otnosheniya po obyazatel'stvam vsledstvie prichineniya vreda zhizni ili zdorov'yu grazhdanina] // Rossiyskaya gazeta. No. 24. Febr.5, 2010.

Illustration 3. FATV Flip

Source: official site of Sber ecosystem.

6. Socio-economic challenges

The government's Concept anticipates that a large-scale introduction of DTVs would strengthen road traffic safety levels and expects hundreds of billions of rubles in savings resulting from the prevented damage that could have resulted from traffic accidents[20]. It should be noted that these socio-economic effects are fully in line with the sustainable development goals which should be achieved by 2030, as set forth in UN's document issued in 2015. At the very least, the Concept's provisions arguably correspond with Goal 9 "Industrialization, innovation and infrastructure," Goal 11 "Sustainable cities and communities," and Goal 12 "Responsible consumption and production"[21]. So, development of driverless vehicles is also in line with our country's main strategic development documents, many of which are in line with UN's sustainable development goals as well.

[20] Section X of the Concept of Ensuring Traffic Safety on Public Roads with Driverless Transportation Vehicles.

[21] For more information, see UN's official site devoted to sustainable development. Available at: https://www.un.org/sustainabledevelopment/;https://un.org/sustainabledevelopment/ru/sustainable-development-goals in Russian (accessed: Oct.1, 2021)

The issues associated with the use of DTVs touch not only on the subject of apportioning tort liability but also on some other issues, such as problems of cyberspace. Thus, a DTV utilized as a taxi is certain to accumulate a wealth of "big user data," ranging from tunes preferred by passengers, their routes, favorite restaurants and stores to reams of videos of streets, other vehicles, and pedestrians (according to SberAutoTech's estimates, one day's worth of data collected by a vehicle amounts to 2 terabytes). In relation to this data, the DTVs' software must be protected in line with the laws on personal data protection and, considering the transborder nature of legal relations, these laws include both Russian[22] and supranational acts — in particular, the European General Data Protection Regulation (GDPR)[23]. Passengers of DTVs will have to provide informed and voluntary consent to personal data processing; they are also entitled to know what sort of data the HATV's possessor collects and uses. Introducing into the software's (for instance, a mobile application's) algorithm a clause of user's acceptance of the privacy policy of the company possessing the HATV appears to be a fairly formal measure, although this problem is of a general nature and cannot be reduced only to the problem of the use of HATVs.

The anticipated changes will probably include not only the described economic benefits from the large-scale utilization of DTVs for cargo delivery; these developments would arguably have a serious impact on the road infrastructure as well. Road networks and parking spaces in big cities would be used more rationally because HATVs would not have to stand idle for hours waiting for their operators — they can go home, to a gas station or a service station by themselves and then return by the time dictated by the operator. Besides, HATVs have a smoother driving style, which should reduce the fuel consumption level compared to the average vehicle and maybe even improve the environmental situation citywide.

The governmental Concept mentions a number of socio-economic risks associated with the development of DTVs. Labor markets are certain to be affected: taxi drivers and truck drivers in big urban centers may well go the way of chimney cleaners and coachmen. A more delicate handling of

[22] Federal law No. 152-FZ (July 27, 2006; as amended on July 2, 2021) On Personal Data [O personal'nykh dannykh]. Compendium of Laws of the Russian Federation [Sobranie zakonodatel'stva Rossiyskoy Federatsii], July 31, 2006, no. 31 (part 1). Art. 3451.

[23] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R06799 (accessed: Oct. 1, 2021)

driverless automobiles will significantly reduce the number of their visits to service stations, and in terms of national economy, the subsequent decline in the number of road accidents will affect the structure of workplaces in car care industry and the demand for car parts. This will strongly affect global logistics chains of raw materials extraction and processing and car parts manufacturing and sales. Other professional groups at risk of downsizing include road safety engineers, traffic police and some others. International researchers note, however, that even in the 1940s public discussions of the risks of unemployment caused by technological advancements were so commonplace that newspapers called them "an old topic" [Susskind D., 2020: 40]. Whereas in fact in the 20th century there was perhaps only one profession eliminated by technological revolutions — that of an elevator operator.

At the same time, one cannot rule out the prospect of DTVs giving rise to negative models of social behavior, from "new luddites" protesting against automation of their workplaces to the possible rise of "pedestrians' extremism," when pedestrians, confident that a DTV would pull up and let them cross the street, will en masse stop observing the road rules crossing streets. That said, it is difficult to imagine that in the nearest 10-20 years streets of Russian cities will have DTVs in the numbers necessary to effect such developments.

In the area of traffic safety, developed countries not infrequently adopt programs intended to eliminate the probability of harmful consequences: zero waste — zero polluting emissions from automobiles; vision zero — zero fatalities caused by traffic accidents. Although the declared goals are noble, these programs appear somewhat utopian because, in this writer's opinion, using machines, one simply cannot avoid accidents. With that in mind, international risk assessors have conceived and developed the standards such as ALARA (As Low As Reasonably Achievable) and ALARP (As Low As Reasonably Practicable). The only effect of the attempts to perpetuate the zero risk requirement would be a slowing down of the development of these technologies, whereas the ALARA and ALARP principles, which are applied, inter alia, in civil aviation, appear to be the most efficient solution.

Some conclusions

By way of a conclusion let's say that in addition to the use of HATVs, there are many other technology-driven experiments being carried out on Russian public roads, but no other field project generates so much interest among the public as this one. What explains this is perhaps the fact that

in mass culture driverless automobiles and robotized public transport are some of the most compelling symbols of the good things technology can bring us in the future. These realities are associated with safety, comfort and economic security while also carrying new risks for the conveniences that humankind is accustomed to, thus generating a public demand for a balanced and fair legal regulatory framework.

As has been aptly noted by philosopher N. V. Stolbova, unlike specialized vehicles, driverless automobiles are integrated into the fabric of everyday life; their presence, their closeness is important for any person irrespective of his/her profession or affiliation with a social group [Komarov S.V., Stolbova N.V. et al., 2019: 58]. Apparently, in the near future driverless automobiles will continue to ply our country's roads and finally will significantly change our tort, insurance and administrative laws.

Conservative-minded people fairly criticize modern drivers for their excessive reliance on electronic assistance systems, low attention levels in the driver's seat, and a lack of technical knowledge about automobiles. But one should not expect that the human skill of car driving will dissolve into redundancy in the nearest decades. It appears more likely that the immediate effects of the development of HATVs in the years ahead would include a greater traffic safety, better economic results for the production chains, and environmental improvements.

This writer believes that the logic underpinning the public authorities' actions — the logic that this article explores — deserves support. 2022 will see the end of the current legal experiment in the use of HATVs with engineers in the driver's seat on public roads; this experiment is to be followed, if the necessary order is issued, by a second stage. During this second phase, in 2022-2024, HATVs will first be running with an engineer in the driver's seat and then, in a remote routing mode, operated from the control center. If this phase is successful, in 2025 the amendments to the federal laws fully legalizing the use of HATVs on public roads would come into force.

The appropriate conceptual basis for the emerging legal regulatory framework could be the thesis that all or, at least, the absolute majority of technological innovations, beginning from the most primitive tools, have served a humanist purpose — making people's life easier, saving their energy, time or other resources. As the civilization progressed, relieving people of the need to do physical work, it freed up more and more time and energy for cognitive activity, for spiritual and intellectual development, enhancing the value of a human life grew and facilitating new discoveries. So, protecting the essential civil rights and liberties should be the primary goal for lawmakers to pursue in the new technological environment.

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The Usage of Musical Works in the Internet within the Russian Law: a Comparative Analysis within the Law of US and EU

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Abstract

The article analyzes the "making available" power presented in Russian copyright law, as well as the specifics of obtaining permission to use musical works and phonograms on the Internet. The right to "make available" has been known to Russian law since 2004. This eligibility appears to be very close to the traditional uses of works that existed long before the advent of the Internet. These include, in particular: public performance, broadcasting and cable retransmission. At the same time, "making available" power is presented in Russian law less fully than the indicated powers. The Civil Code of the Russian Federation describes in sufficient detail the mechanism for obtaining permission by users of musical works and phonograms in the case of their public performance, broadcasting or cable retransmission. In particular, broadcasting organizations, which include radio stations and television companies, as well as users of the public sphere, such as theaters, museums, cinemas, etc., are authorized for the respective uses of works and phonograms through collective rights management organizations. Such organizations represent the interests of rightholders when interacting with users and conclude either licensing agreements or agreements on the payment of remuneration with the latter. Among other things, the Civil Code provides for certain cases of endowing collective rights management organizations with accreditation, which allows issuing permission from an unlimited circle of rightholders, including foreign ones, as well as those who have not entered into an agreement on the management of rights with such an organization. At the same time, recently more and more works and phonograms are distributed on

the Internet. Online cinemas, TV channels, theaters, museum exhibitions, etc. are gaining wide popularity. These resources also use musical works and phonograms, similar to using offline. However, it should be noted that there is legal uncertainty in Russian law related to the mechanism for obtaining permission to use works and phonograms on the Internet. The content of the powers presented in the law of Russia for making a work available, its public performance, broadcasting, communicating by cable, as well as the scope of accreditation, do not allow us to unambiguously conclude about the application of the existing mechanism for obtaining permission through the relevant collective management organizations.

Keywords

Internet, public performance, broadcasting, cable retransmission, retransmission, making available, communication to the public

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Introduction

With the development of technologies, the relations associated with the use of objects of copyright and related rights have changed. To maintain a balance of interests between society and rightholders, in exchange for the use of works on the basis of licenses, the laws of many countries introduced a regime of remuneration to rightholders[1], which is provided in Russian legislation by the relevant articles of the Civil Code[2], and is implemented through the so-called blanket licenses [Boucher F.C., 1987: 1158][3] issued by collective management organizations (herein after referred as CMO). Such remuneration in accordance with Article 1226 of the Civil Code of the Rus-

[1] European Union. Remuneration of authors and performers for the use of their works and the fixations of their performances, 2015. Available at: http://publications.europa.eu/resource/cellar/c022cd3c-9a52-11e5-b3b7-01aa75ed71a1.0001.01/DOC_1 (accessed: 26.04.2020); http://www.aepo-artis.org/usr/files/di/fi/2/AEPO-ARTIS-study-on-performers-rights-1-December-2014-FINAL_201611291138.pdf (accessed: 26.04.2020), https://www.cedar.nl/uploads/10/FileManager/SAA_white_paper_english_version.pdf (accessed: 26.04.2020), etc.

[2] Articles 1263 (3), 1270 (6-8)(2), 1326 Civil Code of The Russian Federation

[3] Available at: https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=2822&context=wlulr; https://www.ascap.com/search-results?q=blanket%20license; https://www.songtrust.com/music-publishing-glossary/glossary-blanket-license; https://www.prsformusic.com/-/media/files/prs-for-music/licensing/application-forms/programme-sales-licence-guide.pdf (accessed: 26.04.2020);

sian Federation refers to "other rights" [Gongalo B.M., Kalyatin V.O., Kirillova M.Ya. et al., 2014: 85]. In accordance with clause 36 of the Resolution of the Plenum of the Supreme Court of the Russian Federation of 04.23.2019 N 10 "On the application of part four of the Civil Code of the Russian Federation" and on the basis of clause 5 of Article 1229 of the Civil Code, the right to remuneration is included in the exclusive right, which also noted in the legal literature [Mikhailov S.M., Morgunova E.A., Ryabov A.A. et al., 2014: 70]. In accordance with clause 1 of article 1244 of the Civil Code, the collection and distribution of such remuneration is carried out by an accredited CMO, which receive accreditation from the Ministry of Culture of the Russian Federation for areas of activity directly established by the Civil Code.[4] The identified areas of activity relate to the following use rights: public performance, broadcasting and / or cable retransmission.

Public performance by law means the presentation of a work in live performance or with the help of technical means (radio, television, etc.), as well as the display of an audiovisual work in a place open to the public, or in a place with a significant number of persons who do not belong to the ordinary family circle, regardless of whether the work is perceived at the place of its presentation or in another place at the same time as the presentation of the work (Article 1270 of the Civil Code; clause 93 of the Resolution of the Plenum of the Supreme Court of the Russian Federation).

Under the broadcasting or a cable retransmission, that is, under the communication to the public (including display or performance) on radio or TV, it should be understood as a direct broadcast of the work from the place of display or performance and repeatedly retransmission of the recorded performance. The broadcasting is carried out by TV or radio company in accordance with the terms of the license agreement concluded between it and the right holder or the Organization for Rights Management (Article 1270 of the Civil Code of the Russian Federation; §94 of the Resolution of the Plenum of the Supreme Court of the Russian Federation).

These legal powers are widely used in various areas of our daily activities. The examples are the use of the phonograms in theatre performances, concerts, sports competitions (ice dancing, synchronous swimming, etc.), exhibitions, etc. The activity of radio stations, TV channels and cable operators is directly related to the legal power of broadcasting or / and cable retransmission, respectively. It is for such "classic" ways to use works / pho-

[4] Ministry of Culture of Russian Federation. Available at: URL: https://culture.gov.ru/documents/akkreditatsiya/ (accessed: 25.09.2021)

nograms the legislations of many countries provide for a mechanism for the implementation of copyright through the CMO.

In this regard, it is important to note the role of CMO, whose activities have been considered from the very beginning as a compromise between copyright protection on the one hand, and the development of those activities in which the use of phonograms plays a significant role, on the other hand. It is the intermediary activities of CMO to represent the interests of copyright holders in collaboration with users, that provided that stable balance, which was and remains extremely important for the implementation of copyright.

However, with the development of the Internet and digital data transmission technologies (Mobile, Bluetooth, etc.) for users such as: Internet radio stations, Internet TV, online cinemas, etc., the problem of legitimate use of works and phonograms is extremely acute. Modern Russian law does not give an unequivocal response, how existing norms allow you to use the traditional mechanism for obtaining the permission through the CMOs currently operating in the Russian Federation. Will the license from the CMO be sufficient to avoid additional claims from the copyright holders?

To answer these questions, it seems necessary first of all to apply to the analysis of the content of Internet rights as in Russian, and in international and foreign legislation. The Russian Federation is a member of all existing international author-legal contracts. Many copyright laws known to the Russian law were borrowed from international standards. Sometimes such borrowing happened "blindly", i.e. without a proper understanding of the content of the right and without a deep analysis of the relevant legal relations. The purpose of this article is the analysis of international treaties and norms of Russian law in terms of copyright regulation on the Internet.

1. Genesis of the Internet copyright law on the international level

Internet copyright in the meaning of the author's right to distribute his work in the digital environment appeared in Russian legislation in 2004. However, the emergence of this authority should be associated primarily with its recognition at the international level. In 1996, it was enshrined in two treaties of the World Intellectual Property Organization: the WIPO Copyright Treaty (hereinafter — WCT) and the WIPO Performances and Phonograms Treaty (hereinafter — WPPT), to which the Russian Federation joined in 2008.[5] It should be noted that the term "Internet copyright"

[5] Treaties for which WIPO is the depository. Available at: https://www.wipo.int/treaties/ru/ShowResults.jsp?lang=ru&treaty_id=16 (accessed: 01.04.2020)

is collective and refers not only to the Internet, but to the digital environment as a whole [Szczepańska B. 2004: 4] [6] Already at the stage of the adoption of this power, it was noted that Internet technologies blurred the boundaries between two traditionally distinct groups of rights: the rights associated with obtaining a copy of the work (the right to distribute, the right to rent, etc.), and the rights not associated with receiving a copy (the right to public performance, the right to broadcast, etc.).[7] In this regard, it was noted that there are two alternative approaches [Christie A.F., Dias E., 2005: 237–262][8], in particular: the application of the distribution right (UK, USA) [Benley L., Sherman B., 2004: 231] and the application of the right to communication to the public (France) [Lipzig D., 2002: 161]. The latest edition of the 1971 Berne Convention[9] already contained redundant provisions[10], namely: "public performance", "communication to the public", "public communication", "broadcasting" and other forms transfer of a work in relation to a limited number of works [Ginsburg J.C., Treppoz E., 2015: 314]. That is why clause 1 of article 8 of the WCT specifically indicates the absence of any conflict and contradiction with the corresponding articles of the Berne Convention, providing for ways of distributing a work, in particular, articles 11 (1) (ii), 11 bis (1) (i), 11 bis (1) (ii), 11 ter (1) (ii), 14 (1) (ii) and 14 bis (1).

The dilemma about the form of providing the Internet copyright in an international treaty arose already at the stage of negotiations. Members of the WIPO Committees[11] discussed two competing powers presented through the right of reproduction, and then, alternatively, either 1) with the granting of a wider distribution right, or 2) in conjunction with the corresponding communication right enshrined in the Berne Convention. However, the conflicting positions of the US and the EU led to a compro-

[6] Available at: https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1717&context=iatul (accessed: 20.05.2021)

[7] WIPO. The Manual for the Agreements on Copyright and Neighboring Rights. Geneva, 2003. P. 207.

[8] Available at: https://minerva-access.unimelb.edu.au/bitstream/handle/11343/25131/Christie_Dias_The+new+light+of+communication.pdf;jsessionid=12079866CD69209442D5D7F90EAEB01A?sequence=3 (accessed: 15.04.2020)

[9] The Berne Convention for the Protection of Literary and Artistic Works.

[10] Revision of the Berne Convention in Paris in 1971. Available at: https://www.wipo.int/treaties/ru/ip/berne/summary_berne.html (accessed: 15.04.2020)

[11] See in details: WIPO, Diplomatic Conference on certain copyright and neighboring rights questions Geneva, December 2 to 20, 1996, clauses 7.05, 7.07, 7.08, 7.12 etc. Available at: https://www.wipo.int/edocs/mdocs/diplconf/en/crnr_dc/crnr_dc_4.pdf (accessed: 15.04.2020)

mise, "umbrella solution" [Peter K. Yu., 2010: 576], which was eventually included in the corresponding articles of the WCT and WPPT [WIPO, 2003: 208].

In this regard, according to a study by the US Copyright Office, at present we can talk about the existence of at least three approaches to the regulation of "Internet copyrights" in national legislation:[12]

the so-called "Approach identical to the international treaty", which implies full, or very close to the original with minor adjustments, copying of Article 8 WCT, as well as Articles 8, 14 WPPT. In this approach, the right to "make available" is part of the right to "communicate to the public". Thus, a broad approach to the right of communication to the public for use in the digital environment is being shaped. Since the communication to the public is a "traditional" right and was known to the law of many countries before the adoption of the WCT and WPPT, most countries, in particular the EU, chose this particular wording to "characterize the new property right, since it was formulated not as completely new one, but as an extension of some of the copyrights previously recognized internationally [Gavrilov E.P., 2005: 20];

an alternative approach, which, as a rule, considers the right to make available as a separate authority (this approach is used in Russia);

Statutory Silence approach: with this approach, the state, being a member of WCT and WPPT, does not in any way change the position of national legislation. The use of works in the digital environment is classified in terms of the existing scope of rights to use the work that existed before the accession to these agreements, as well as the appearance of digital use (USA).

Such a difference in approaches to understanding the right to Internet law could not but affect national legislation, in particular, of Russia, the USA and the EU.

2. Comparative analysis of Internet copyright law in the jurisdictions of Russia, the USA and the EU

The "Internet copyright law" presented in Russian legislation was first adopted in 2004 as amendments to the Law "On Copyright and Related

[12] US Copyright Office. The making available right in The United States. A Report of the Register of copyrights, 2016, Appendix E. Survey of foreign laws regarding statutory approaches to the right of making available. Available at: https://www.copyright.gov/docs/making_available/making-available-right.pdf, (accessed: 15.04.2020)

Rights" of 09.07.1993 N 5351-1 (hereinafter referred to as the Copyright Law).[13] The emerging norms could not but cause a certain resonance in society, because completely new relations emerging in an environment previously unknown to mankind were subject to legal regulation. The of copyright regulation on the Internet still remains highly controversial [Wunsch-Vincent S., 2013: 9]; [Edwards L., 2010].

The Copyright Law granted the author (Art.16), performer (Art.37) and phonogram producer (Art.38) the right to communicate the work (performance and phonogram), in such a way that any person can have access to it online from any place and at any time (the right to make available). The wording of these articles has been cited in a number of court decisions, without in-depth analysis of the norms.[14]

Despite the fact that in Russian legislation the "Internet copyright" has existed since 2004, its content and scope is still controversial. It seems that the new right to use the work was not fully regulated in the 1993 Law on Copyright and Related Rights, but only in such a version as to ensure the compliance of the Russian legislation with WCT [Gorlenko S.A., Kalyatin V.O., Kiriy L. L. et al. 2016: 76]. Some authors consider this Russian norm to be an unsuccessful copy of the corresponding article of the WTC [Kalyatin V.O., 2005: 3].

However, the current version of this authorization does not appear to cover all possible uses of works / phonograms on the Internet.

After the reform of civil legislation in 2008, the content of the right to "make available" underwent certain changes.

The current Civil Code of the Russian Federation grants Internet copyrights to the author (Article 1270), to the performer (Article 1317) and to the producer of the phonogram (Article 1324). The broad wording "making available" is used to refer to cases where works are posted on the Internet in such a way that anyone can access the work from anywhere and at any time of their choice. In this sense, "making available" should be understood as the granting of the right of access and further control over the transfer of the work [Rozhkova M.A., 2018: 55]. When comparing the content of the right to make available in the 1993 Law on Copyright and Related Rights and the Civil Code of the Russian Federation 2008, the following differ-

[13] Federal Law of 20.07.2004 N 72-FZ "On Amendments to the Law of the Russian Federation" On Copyright and Related Rights". Rossiyskaya Gazeta. 03.08.1993.

[14] Resolution of the Thirteenth Arbitration Court of Appeal of 29.05.2009 in case No. A56-32763 / 2008 // SPS ConsultantPlus.

ences are revealed: firstly, in the Civil Code, use is presented in "making available", as a way of presenting a work in a digital environment, and not in "broadcasting", which, probably, in the opinion of the legislator, differs from the activities of TV and radio organizations and cable operators; secondly, in the Civil Code of the Russian Federation there is no concept of "interactive mode", but it is understood that communication to the public is associated with the use of works on the Internet.

The content of this right was perceived critically by Russian researchers. In particular, it was noted that "making available to the public" is not a right of use at all, but a result that can be achieved in various ways, for example, by transmitting a work by radio or TV [Kalyatin V.O., 2005: 3]. Vitaly Kalyatin also emphasizes that "making it public is not a way of using a work that is typical exclusively for the Internet; it is not a way of using a work at all" [Kalyatin V.O., 2004: 3]. A number of researchers noted that this right should be considered either as a separate power, for example, reproduction [Pogulyaev V.V., Vaipan V.A., Lyubimov A.P., 2006: 77], duplication of the right of retransmission by cable [Eremenko V.I., 2005: 68–75], or as a complex of rights, consisting of the right to reproduction, public display, public performance, broadcast and retransmission to the public by cable [Gavrilov E.P., 2005]. We agree with many researchers — Vitaly Kalyatin, Eduard Gavrilov and others who questioned the need to recognize the "right to make available" as a separate power. Indeed, those powers that were previously known to copyright fully correspond to the volume and nature of the use of works. Only the environment and the method of delivery of the works have changed. The legislation of the Russian Federation before the changes in 2004 was completely dispensed with by those powers — reproduction and distribution — which were known to Russian law.

This is the approach used in US law, where Internet copyright law was implemented with the adoption of the DMCA (Digital Millennium Copyright Act) in 1998.[15] However, the DMCA does not contain any specific "internet" entitlement. This is due to the position of the United States, according to which the use of works on-line is actions within the existing exclusive copyright powers, named in the law, related to reproduction, distribution, public display and public performance.[16] In addition, to ex-

[15] The Digital Millennium Copyright Act 1988. Available at: https://www.copyright.gov/legislation/dmca.pdf (accessed: 12.04.2020)

[16] Internet policy task force. U.S. Dep't of Commerce. Copyright policy, creativity, and innovation in the digital economy 15 (2013) ("Green Paper") Available at: http://www.uspto.gov/news/publications/copyrightgreenpaper.pdf, P14-18 (accessed: 12.04.2020)

isting reproduction and public performance rights, the distribution right enacted in the 1976 Copyright Act applies to digital transmissions in the same amount as to tangible media.

In the United States, digital communication rights are applied only in relation to sound recordings (phonograms). After analyzing Internet contracts, as well as domestic legislation, considering the established judicial practice and the opinions of leading academic institutions, the US Copyright Office concludes that for the rest of the protected copyright works, a set of "traditional" use rights for the digital environment should be applied, which constitutes a single power to "make available". In this sense, for all issues arising both online and offline, the traditional mechanism for clearing rights from copyright holders will be applied. For example, the act of downloading a work complies with the distribution right (clause 3 § 106 of the Copyright Act); the act of streaming (broadcasting) or displaying an image on the Internet is understood as the right of public performance and public display in accordance with clauses 4-6 §106 of the Copyright Act, etc.[17]

The EU regards internet copyright as an extended power to communicate to the public that is set out in various Directives.[18] The right to communicate to the public was broadly interpreted in EU Directive 2001/29 / EC of 22.05.2001 "On the harmonization of certain aspects of copyright and related rights in the information society", known as the InfoSoc Directive (hereinafter referred to as the Copyright Directive)[19]. One of the objectives of this directive was to establish uniform norms for the ratification of the

[17] US Copyright Office. The making available right in The United States. A Report of the Register of copyrights. Wash., 2016, P.15-55. Available at: https://www.copyright.gov/docs/making_available/making-available-right.pdf (accessed: 15.04.2020)

[18] Directive 93/83/EEC of 27 September 1993 on the coordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission; Directive 92/100/EEC of 19 November 1992 on rental right and lending right and on certain rights related to copyright in the field of intellectual property; Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases; Directive 2014/26/EU of the European Parliament and of the Council of 26 February 2014 on collective management of copyright and related rights and multi-territorial licensing of rights in musical works for online use in the internal market); Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC.

[19] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32001L0029 (accessed: 01.10.2021)

WCT and WPPT by the EU member states related to digital use, including with respect to making available, which should be understood in a broad sense, covering all types of communication for the public (Article 23 of the Introductory Provisions of the Copyright Directive). Article 3 of the Copyright Directive based on Article 8 WCT contains a provision according to which "… Member States shall provide authors with the exclusive right to authorize or prohibit any communication to the public of their works, by wire or wireless means, including the making available to the public of their works in such a way that members of the public may access them from a place and at a time individually chosen by them. " The first part of this article deals directly with the communication for general information, the second part — the so-called. "Sub-right" — known in Russian law as making availible rights, which is part of the basic right of communication to the public and cannot be interpreted outside this context [Koo J., 2019: 81]. Making available is an act of access for the transmission of a work on demand, and applies regardless of whether it is directly transmitted [Savola P., 2017: 3]. In the EU, communication to the public should be considered in two aspects: "traditional", associated with the use of works (phonograms) through public performance and broadcast / cable communication and "digital", i.e. use on the Internet [Koo J., 2019: 90]. A broad interpretation of the right of communication to the public on the Internet was given by the European Court of Justice, which noted that "... the concept of 'communication to the public', within the meaning of Article 3 (1) of Directive 2001/29, must be interpreted as meaning that it covers a retransmission of the works included in a terrestrial television broadcast:… .by means of an internet stream made available to the subscribers of that other organization who may receive the retransmission by logging on to its server… ".[20]

A broad interpretation of the right to communicate to the public is observed even in those Directives that do not explicitly mention this right [Frankel S., Gervais D., 2016: 217], as well as in the legislation of many EU countries.[21] In particular, the Swedish copyright law, like other Nordic countries, contains a rule on the universal right to make available, which is covered by the right of communication to the public, by means of wired

[20] Judgment of The Court (Fourth Chamber) in CaseC-607/11 7 March 2013. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62011CJ0607:EN:HTML (accessed: 22.04.2020)

[21] The International Literary and Artistic Association. Report and opinion on the making available and communication to the public in the Internet environment — focus on linking techniques on the Internet, pp. 4, 5. Available at: https://www.alai.org/en/assets/files/resolutions/making-available-right-report-opinion.pdf (accessed: 15.04.2020)

and wireless communications (paragraphs 1, 4 of article 2 of the Law on copyright).[22] German copyright law deals with several entitlements within a broad approach to the right to communicate to the public, including the right to make available (Art 15 Urheberrechtsgesetz).[23] The UK Copyright Act recognizes as violation of the right to communications for the public to misconduct by bringing a work to the public, a right that is reserved to the copyright holder in section 16 (1) (d) of the said act.[24]

3. The Internet copyright law in Russian legislation

Based on the analysis of the content of Internet law in international treaties — Article 8 of the WCT and in the corresponding articles of the WPPT, as well as regulation in US and EU law, we can note the peculiarities of the Russian approach to Internet copyright law. In particular, international treaties grant the author and the producer of the phonogram the exclusive right to permit any communication to the public[25], by wire or by means of wireless communication, which includes the right to make available to the public. It is this right — any communication for the public, along with the right of distribution — that became the object of study in the adoption of WIPO international Internet treaties in the aspect of digital use.

According to the WIPO Glossary, communication to the public should be understood to mean the provision of a work, performance, phonogram or broadcast, appropriately perceived by anyone, not limited to specific individuals belonging to a private group. It is broader than publication and includes uses such as public performance, broadcasting, communicating to the public by wire, or receiving a broadcast signal directly [WIPO, 1980: 42]. This approach differs from the right to make available which exists in Russian legislation. Disclosing the concept of "message", the Civil Code of the Russian Federation indicates that such is any action by means of which a work becomes available for auditory and (or) visual perception, regardless of its actual percep-

[22] Act (1960:729) on Copyright in Literary and Artistic Works (as amended up to Act (2018:1099). Available at: https://wipolex.wipo.int/en/text/495847 (accessed: 15.04.2020)

[23] Act on Copyright and Related Rights (Copyright Act, as amended up to Act of September 1, 2017). Available at: https://wipolex.wipo.int/en/text/474282 (accessed: 15.04.2020)

[24] Copyright, Designs and Patents Act of 1988. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/772818/copyright-designs-and-patents-act-1988.pdf (accessed: 15.04.2020)

[25] WIPO Copyright Treaty. Available at: https://wipolex.wipo.int/en/text/295166 (accessed: 20.07.2021)

tion by the public (Article 1270 of the Civil Code). Such an expanded approach to the term "communication", on the one hand, fully complies with paragraph 1 of Article 8 of the WCT, but at the same time, in the wording of this article, it is limited to broadcasting on radio or TV. Understanding the wording of the right to "communicate to public" is further complicated by its content used in the Civil Code of the Russian Federation. If in the first sentence of clause 7 of Article 1270 of the Civil Code we are talking about "communication to the public", then the next sentence contains only the term "communication", without the qualifying feature "to the public."

Thus, in relation to the action associated with the "communication", two mutually exclusive conclusions can be drawn based on the content of article 1270 of the Civil Code of the Russian Federation:

communication is any action, including also broadcasting on radio and TV (extended approach);

communication is only broadcasting on radio and television (narrow approach).

In the light of the provisions of Article 8 WCT, the resolution of the current contradiction is extremely important, since it affects the qualification of certain actions related to the use of objects of copyright and related rights on the Internet and in another digital way (mobile operators, etc.).

According to Article 1329 of the Civil Code of the Russian Federation, an organization that carries out on-air and cable broadcasting is a legal entity. In turn, Art. 31 of the Law of the Russian Federation of 27.12.1991 "On the Mass Media" TV or radio broadcasting is carried out by the broadcaster on the basis of a license granted by an authorized federal body. Obtaining a broadcasting license is not required if the broadcasting of a TV channel or radio channel is carried out unchanged under an agreement with a broadcaster holding a license to broadcast a TV channel or radio channel. The latter should be attributed to individuals such as the cable operator.

In accordance with the Law "On Licensing"[26], TV and radio broadcasting are possible only with an appropriate license issued by the federal licensing body, which is currently the Federal Service for Supervision of Communications, Information Technology and Mass Media (*Roskomnadzor*).[27] The

[26] Federal Law of 04.05.2011 N 99-FZ (as amended on 02.07.2021) "On licensing certain types of activities". Rossiyskaya Gazeta. 06.05.2011.

[27] Federal Service for Supervision of Communications, Information Technology and Mass Media. Available at: https://rkn.gov.ru/mass-communications/license/p156/ (accessed: 15.10.2021)

Law on Mass Media in the Russian Federation considers only a legal entity as an applicant for a license. Consequently, only legal entities are those subjects that carry out communication of a work to the public by radio or TV.

At the same time, the distribution of a work on the Internet can be carried out, among other things, by individuals, as well as by persons who, although they carry out entrepreneurial activities, are not legal entities (for example, individual entrepreneurs, self-employed). In addition, these persons can not only relay programs of TV and radio companies, but also use their content. Nothing also prevents individuals from creating Internet radio and television channels on their own. And this is observed everywhere today: personal channels on YouTube, videos on TikTok, etc.

In this sense, the subject of the use of works / phonograms on the Internet has no meaning for the copyright holders. Another thing is important: the very fact of use. Also of interest is the method and type of use of the work, which allows you to choose a mechanism for clearing user rights.

4. Features of using works on the Internet

Referring to the Internet copy right, represented in Russian law, it should be noted that it is associated with the provision of access to the work / phonogram to any third parties who can access such objects at any time from anywhere. However, as noted above, this too narrow approach to this right does not always allow us to characterize it correctly.

Currently, the following ways of using works in the digital environment (which are not legal categories) can be distinguished:

simultaneous (streaming) broadcasting is a method of broadcasting in which a person carries out "traditional" broadcasting by radio and TV waves (off-line) with simultaneous transmission on the Internet (online). Since, as indicated above, only legal entities can communicate a work to the public on radio or television, therefore, this form of presentation (use) of a work is typical for all radio and TV channels that have a broadcasting license[28];

digital broadcasting is a method of broadcasting only in a digital environment (Internet, through mobile applications, etc.). In this case, there is no need for a person to obtain any license, as well as to register as a special entity (individual entrepreneur, legal entity);

making the work available to the public. These users include online cinemas, digital services, etc. They generally do not stream;

[28] See official web sites of radio broadcasters. Available at: URL: https://europaplus.ru/, https://rusradio.ru/, https://www.1tv.ru/, https://tvzvezda.ru/ (accessed: 15.02.2021)

mixed method: is most often typical for such digital platforms as Yandex Music, YouTube, Spotify, etc., on which both digital broadcasting and making the work available to the public is carried out.[29]

As noted above, these ways of using works in the digital environment are conditional. Another thing is important — in all cases, the use of works occurs and, therefore, a "clearing" of rights is required. And it is the definition of this mechanism — through direct licensing by the rightsholder or through blanket licenses issued by the CMO — that is the problem that needs to be resolved.

5. Simultaneous (streaming) broadcasting

Simultaneous communication on the air and on the Internet turns into a problem for broadcasting organizations, for which it is not always clear what is the act of communication on the Internet and in mobile television, and how to qualify the object of the broadcasting? As M.V. Prokofieva correctly notes, according to article 1225 of the Civil Code, messages on the air or by cable of radio or television broadcasts are the results of intellectual activity, which are granted legal protection as an object of related rights. Simultaneous communication on the air and on the Internet turns into a problem for broadcasting organizations, for which it is not always clear what is the act of communication on the Internet and in mobile TV, and how to qualify the object of the broadcasts? At the same time, when a broadcaster broadcasts its TV channel on the Internet, these methods are not considered as broadcasting the work on the air and, based on the meaning of the norm, are not protected, although in this case the same program of the TV channel is broadcast in real time without changes as on the air and via the Internet, which leads to infringement of the rights of the broadcasting organization [Prokofieva M.V., 2009: 6].

Regarding the obtaining permission to use a work by broadcasting organizations, it is enough to request a license from the relevant CMO.[30] However, the Civil Code of the Russian Federation does not contain a clear answer whether these licenses cover cases of simultaneous (streaming) messages on the Internet and in a mobile application? If so, is it possible to

[29] Official web sites of the providers. Available at: URL: https://music.yandex.ru/home, https://www.youtube.com/?gl=RU, https://www.spotify.com/ru-ru/why-not-available/ (accessed: 05.05.2020)

[30] Licenses issued by CMO. Available at: URL: http://rao.ru/for-users/to-radio/; http://rosvois.ru/contract-tv/ (accessed: 05.10.2021)

extend such licenses to other cases of the message, for example, only online [Ivanov N.V., 2017: 17]?

It seems that the answer should be yes: the blanket license issued by the relevant PMCS is sufficient for streaming. When broadcasting simultaneously, as well as when broadcasting online or in a mobile application, only the receiving method changes for the user.

Digital and Internet broadcasting differs from TV or radio broadcasting only in the transmission medium (IP networks, cable or wireless networks, instead of radio), and coincides in capabilities — the listener in both cases cannot independently choose the content played at a given moment in time, and save it for later listening by regular means. In case of stopping listening to the channel, the user resumes listening not from the place where he left off, but connects to the actual message of the work that is currently being broadcast on the corresponding channel [Sytenko G.I., Vilinov A.A., 2010: 7]. Based on this, Internet broadcasting can also be equated to a special form of broadcasting, but there are no restrictions on a person — a legal entity, individual entrepreneur, etc., which carries it out. As noted above, the presence / absence of special subjects, as well as permits (in this case, licenses for broadcasting activities), does not exclude the very fact of use and requires obtaining a blanket license from the CMO, by analogy with Art. 1244 of the Civil Code of the Russian Federation).

In the case of using a work by making available to the general public, attention should be paid to the work to which access is provided on the Internet. When accessing certain objects, for example, audiovisual works, as well as user content on social networks (eg., Vkontakte) and video hosting (eg., YouTube, online cinemas, etc.), users do not create a request for works that constitute the content of such objects. For example, when watching a movie in an online cinema, the user, by analogy with offline cinemas, refers directly to the film, but not to the musical work used in it. In this sense, it makes no difference for the authors of a piece of music whether it is a public performance, broadcast, or the making a film available to the public. Watching a movie through any special service on the Internet does not differ in any way from watching it in an offline environment (cinema, TV channel, etc.). The only difference is the access to the work in terms of the time of its presentation: in the offline environment, access is possible at a set time by the person performing the public performance and / or broadcasting, while in the digital environment the work is available at any time and from any place at the request of the user.

For persons carrying out the lawful use of audiovisual works both online and offline, the mechanism for obtaining permission from copyright

holders is also the same. In particular, both offline and online cinemas, as well as TV channels, must obtain the corresponding right to use the audiovisual work. However, in no case does the existence of licensing agreements with rightholders exempt licensees from paying remuneration to authors, provided for in clause 3 of Article 1263 of the Civil Code.

The following thesis is also important: the disposing a work on the Internet or in another digital environment does not exclude the fact that it is used in different ways.[31] In particular, in accordance with para 89 of the Resolution of the Plenum of the Supreme Court of Russia of April 23, 2019 No. 10, recording a copy of a work on an electronic medium with the subsequent provision of access to this work to any person from anywhere at any time (also on the Internet) is the exercise of two powers that are part of the exclusive right: the right to reproduce (subparagraph 1 of para 2 of Article 1270 of the Civil Code of the Russian Federation) and the right to make available to the public (subparagraph 11 of para 2 of Article 1270 of the Civil Code of the Russian Federation).

We must agree with the position of the Plenum of the Supreme Court that the power to make available to the public is impossible without the power to reproduce. Indeed, in order for a work to become available on the Internet, it must first be uploaded to the server.

However, one should not be limited only to the specified powers. In certain cases, it can be argued that the power to "make available" is also correlated with the power to broadcast and perform in public. In the examples mentioned above, in particular, in streaming, the communication of the work to the public is actually broadcast. In turn, when providing an audiovisual work for general information, it should be stated that it is also broadcast and / or publicly performed.

Singling out as a separate power as bringing it to the public, the legislator only pursued the goal of emphasizing the environment of use different from the offline one, but no more. As noted above, the use of a work in a digital environment is a collective concept (by which the Plenum understands an information and telecommunications network, including the Internet), does not mean that there is no use of "traditional" powers. It is important to note here that a high level of legal protection can and should be interpreted to mean that copyright holders can control the proper use of their works and receive appropriate remuneration [Depreeuw S., 2014: 616].

[31] There are exceptions related to access to the work, for example, age restrictions, subscription access, etc. However, these exceptions do not replace the general rule for granting access to a work.

Conclusion

Analysis of international treaties, as well as regulatory provisions regarding the regulation of powers related to the use of works / phonograms on the Internet in the United States and the EU shows that this power is presented in a broad interpretation, which makes it possible to clear rights through the legal mechanisms existing provided for by the Civil Code of the Russian Federation. This mechanism is implemented through the system of collective management of rights. A broad approach to Internet law allows flexible application of current legislation to ensure the interests of copyright holders and users, while maintaining the balance necessary for business development. Thus, the stability and stability of legal relations is ensured, which do not depend on the development of technologies.

The existing mechanisms in the Civil Code, if properly interpreted, also allow the current CMO to collect remuneration for the represented groups of copyright holders from users performing streaming, as well as the presentation of musical and audiovisual works on demand. A broad approach to existing powers does not so much expand the powers of national CMO, but rather serve as a guarantee for the normal functioning of users on the Internet. Otherwise, a serious revision of the current rules will be required, which at the current moment will negatively affect not only the copyright holders, but also the users, who may be subject to legal claims for violation of rights, which is associated with the actual suspension of the activities of law-abiding users.

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Contractual Relations with Participation of Performers, Producers of Phonograms and Broadcasting Organizations

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Abstract
In the creative industry, performers' interests cannot be met solely through their own actions and the realization of their own creative abilities. Coordinated interaction of representatives of creative professions and show business is necessary. In this area, various kinds of agreements are concluded, which do not always relate to the exercise of intellectual rights. The Civil Code of the Russian Federation regulates in more detail the contractual relations associated with the use of works of authorship, without paying due attention to contracts with performers, producers of phonograms and broadcasting organizations, which leads to the problem of double interpretation in the process of law enforcement. Performers, producers of phonograms and broadcasting organizations conclude not only agreements on the disposal of exclusive rights, but also agreements on the distribution of remuneration for use, on the management of rights, and others.The article examines some types of civil contracts concerning the objects of related rights. Some contractual relations concerning related rights, both those named in Chapter 71 of the Civil Code of the Russian Federation, and not named in it, but occurring in practice, are analyzed. A comparison is made of similar contractual relations concerning objects of copyright and objects of related rights. It is important to distinguish service contracts involving performers, phonogram producers, and broadcasting organizations from contracts for the exercise of intellectual rights. If in the contracts of the first group special attention deserves the beneficial effect achieved from the actions of the service provider, then

in the second group of contracts the personality of the right holder as a party to the contract, as well as special characteristics of the result of intellectual activity, are of significant importance in the execution of the contract. The user (service recipient) must determine what is of paramount importance to him, since the essence of the contract with the performer, its subject matter and content will depend on this.

Keywords

author, intellectual right, exclusive right, performance, performer, license contract, neighboring rights, phonogram

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Introduction

In an age when scientific progress creates new information technologies and ways of interaction between people, novels poems, songs, musical compositions, scripts and other works would dust on the shelves of libraries, archives and home collections, if performers, phonogram producers, broadcasting organizations could not present it to the public both live, recorded and broadcast.

But involving the exclusive rights to works of art in commercial circulation, interested parties enter into legal relations with their authors, including concluding various agreements with them.

As to the results of the intellectual activity of performers, producers of phonograms, broadcasting organizations, producers of databases and publishers, in accordance with the Civil Code of the Russian Federation, related (neighboring) rights are recognized on the territory of the Russian Federation, and a certain procedure for using objects of related rights is established. Chapter 71 of the Civil Code is devoted to related rights. It reflects some provisions concerning agreements on the disposal of the exclusive right to objects of related rights (agreements on alienation of exclusive right and a license agreement on granting the right to use). General provisions on civil obligations (Articles 307–419 of the Civil Code) and on the contract law (Articles 420–453 of the Civil Code) apply to such agreements. Other types of contracts relating to neighboring rights, in the Chapter 71 of the Civil Code are not mentioned. At the same time, the results of intellectual activity can be created jointly by several persons, and the

rightholders, by agreement of the parties, can determine the procedure for exercising their intellectual rights. The exercise of intellectual rights belonging to the copyright holder is also possible through his representative. In addition, performers give concerts to the public, phonogram producers produce master cassettes, and broadcasting organizations broadcast feature films and other audiovisual works.

But will all contractual legal relations deal with the exercise of the related rights of performers, producers of phonograms, broadcasting organizations and other holders of related rights?

1. Contracts with performers, phonogram producers and broadcasting organizations: some classifications

Legal doctrine provides a wide range of classifications of contracts in the field of intellectual property. For example, some experts identify a system of contracts ensuring the circulation of exclusive rights, which includes contracts for the alienation of exclusive rights[1], contracts for the transfer of exclusive rights, contracts for the provision of services in the field of intellectual property, contracts for representation and management.

E.A. Morgunova, in addition to agreements on the disposal of exclusive rights, distinguishes four more groups of agreements in the field of intellectual property:

contracts directed or related to the creation of results of intellectual property ;

contracts aimed at exercising other intellectual rights;

contracts for the provision of legal services in the field of intellectual property;

agreements on the procedure for the exercise of intellectual rights between their co-holders "[2019: 87][2].

Are all these groups of agreements related to the objects of neighboring rights?

When concluding contracts, one should take into account, in particular, the legal nature of the result to be achieved by the contract, its legal

[1] Agreements providing for the circulation of exclusive rights. Ed. by Sannikova L.V. Moscow, 2018. 184 p.

[2] Intellectual property: issues of legal protection. Moscow, 2019, p. 87.

characteristics, legal facts that are the basis for the provision of particular rights, rights and obligations of the parties and the amount of transferred or granted rights.

It is possible to distinguish a separate group of contractual relations with the participation of performers and publishers, which are aimed at the use of objects of related rights. And it is advisable to distinguish such a group from contractual relations with the participation of these persons for the provision of services in the field of show business.

On the one hand, if a viewer buys a ticket for a performance, he enters into a contractual relationship with the performer for the provision of a service. As a result of the provision of such a service, the result of intellectual activity arises — a performance. But the legal relationship between the viewer and the performer for the provision of the service does not apply to the further public use of such a performance. The same situation arises when a performer or his producer is interested in popularizing a performance and enters into an agreement with a broadcasting organization for broadcasting this performance on radio or television. On the other hand, if a broadcasting organization or other person has an interest in using, for example, by recording and / or broadcasting or by cable, a performance, it needs to conclude an agreement with the performer on the disposal of the exclusive right to the performance.

In the first example, we can talk about a service contract in the field of show business, and in the second one, about an agreement on the disposal of an exclusive right. In an agreement on the disposal of an exclusive right (in relation to the cases described above), the subject is the object of related rights.

In the contract for the provision of services, as a subject should be considered the activity of performers, broadcasting organizations, or the publisher (in some countries, this category of subjects also includes producers, organizers of entertainment events), aimed at the intangible effect arising when presenting performances. At the same time, in such a group of contracts, there is a connection between the provided service and the personality of the performer, the result of the performed activity itself does not exist in isolation from the performer under the contract. Agreements for the provision of services in the field of and show business (in this article, this concept is used in a broad sense) can conditionally include an agreement on the creation of a master cassette, an agreement for the provision of services to subscribers by a cable operator, a trust management agreement, a receipt agreement, an agency contract and others.

The practical value of the division of contracts concerning the results of intellectual activity into the two indicated groups is expressed, for example, in some differences in the methods of legal protection used in cases of violation of rights during the execution of contracts.

Let us consider in more detail some types of these contracts in relation to performances, phonograms, databases, broadcasting and works made public after the death of the author.

2. Contracts on the disposal of exclusive rights

Agreements on the disposal of exclusive rights include agreements on the alienation of exclusive rights, a license agreement on the grant of an exclusive right, a pledge agreement, and a commercial concession agreement. The agreement on the alienation of the exclusive right presupposes the transfer of the exclusive right to the results of intellectual activity and means of individualization in full (Article 1234 of the Civil Code of Russia). The transfer of exclusive rights is allowed in relation to all objects of related rights (Article 1307 of the Civil Code); restrictions on such transfer are not provided by law. As to inventions, utility models, industrial designs or trademarks, their legal protection is limited to the territory of the state or region in which such an object is registered.

With regard to an object of copyright, when concluding an agreement on the alienation of an exclusive right, the parties often indicate in the texts of agreements the transfer of exclusive rights on the territory of the whole world, meaning by this the states where copyright protection of such a work is in effect, and these are 177 states parties to the Berne Convention on the protection of literary and artistic works, including the Russian Federation[3]. As for the objects of related rights, the approach to the transfer of exclusive rights requires additional attention. Objects of related rights created in the Russian Federation are protected not only in the Russian Federation, but also in other countries, including on the basis of the principles of reciprocity and in accordance with international treaties. There is no single international treaty concerning all objects of related rights. The provisions on the rights of performers, producers of phonograms and broadcasting organizations are enshrined in several multilateral international treaties that provide provisions on national treatment to be accorded to foreign

[3] See: Berne Convention for the Protection of Literary and Artistic Works. Contracting Parties. World Intellectual Property Organization. Available at: https://www.wipo.int/export/sites/www/treaties/en/documents/pdf/berne.pdf (accessed: 01.09.2019)

rightholders. Such international treaties include the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome, October 26, 1961, hereinafter referred to as the Rome Convention,[4] Article 2), the WIPO Performances and Phonograms Treaty (Geneva, December 20, 1996,[5] Article 4), Agreement on Trade-Related Aspects of Intellectual Property Rights (Article 3).[6]
The Convention on the Distribution of Program-Carrying Signals Transmitted by Satellite (Brussels, May 21, 1974) and the Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms (Geneva, October 29, 1971) do not grant international legal protection to the broadcasts of broadcasting organizations and phonograms, respectively, but only provide legal guidance for such protection at the national level of the contracting parties through the adoption of remedial measures in case of violations. Since the Russian Federation participates in multilateral international acts including, the above mentioned in the field of intellectual property, the performance of Russian artists, the phonograms of Russian phonogram producers and the broadcasting of broadcasting organizations are protected, and the rights to them can be transferred by agreement in those states where such objects are granted security.[7]

At the same time, the international treaty providing for special international legal protection of databases, which in Russia are recognized as objects of related rights, remained at the stage of the project considered by the Standing Committee on Copyright and Related Rights of the World Intellectual Property Organization. Also, there is no international protection of the publisher's rights, although a number of European countries provide legal protection to the publisher. In this regard, the rights of producers of databases and publishers are recognized in various countries and protected on the basis of the principle of reciprocity.

[4] 94 participating states as for March 2019: International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations. Contracting Parties. World Intellectual Property Organization. Available at: https://www.wipo.int/export/sites/www/treaties/en/documents/pdf/rome.pdf (accessed: 01.09.2019)

[5] 102 participating states as for May 2019: WIPO Performances and Phonograms Treaty. World Intellectual Property Organization. Available at: https://www.wipo.int/export/sites/www/treaties/en/documents/pdf/wppt.pdf (accessed: 01.09.2019)

[6] National regime for performers, manufacturers of phonograms and broadcasting organizations by agreement Agreement on Trade-Related Aspects of Intellectual Property Rights applies only to the rights provided for by this Agreement. (164 WTO member).

[7] At the same time, it is necessary to take into account the features of the transfer of rights provided for by national legislative acts of participants in international treaties.

In the legislation of other countries with respect to objects of related rights, a different (compared to that provided for in the Russian Federation) legal regime may be granted, for example, in Great Britain, broadcasting is considered as an object of copyright. In addition, in various countries, approaches to the disposal of exclusive rights differ. For example, in Japan related rights can be transferred in full or in part (Articles 103 and 61 of the Japanese Law of May 6, 1970 «On Copyright» as amended), in Germany, as a rule, they talk about licensing agreements. In addition, with regard to performers, §§ 78 and 75 of the German Act of 9 September 1965 on Copyright and Neighboring Rights stipulates that the rights of recording, reproduction and distribution, as well as the right to receive remuneration for the rental and provision of video or audio carriers for free use cannot be ceded.

Thus, the scope of legal protection, one of the characteristics of which includes the territory of validity of the exclusive right, will be subject to clarification each time. So, for example, experts propose, when alienating the exclusive right to a database, to indicate all states on whose territory this right is transferred, since if the corresponding state is not indicated, the exclusive right in such a state will not transfer [Kalyatin V.O., 2018: 107]. This position seems to be debatable, since in order to alienate the exclusive right, the copyright holder must define in the contract all those countries where his object is protected. Otherwise, it cannot be said unequivocally that the exclusive right will pass to the acquirer in full, and any limitation of the right under the contract gives grounds to be considered in accordance with the Civil Code of the Russian Federation as a license agreement (clause 3 of Article 1233).

In some cases, the legislator made the moment of transfer of related rights dependent on the need and possibility of state registration of the result of intellectual activity. The right to use the object of related rights is granted, and the exclusive right to the objects of related rights is transferred, as a rule, at the time of signing the agreement or within the period specified in the agreement. For the provision of legal protection to objects of related rights, the exercise and protection of rights to them, as well as to objects of copyright, no state or other registration, deposit or any other formalities are required. At the same time, if the object of related rights is a database, its rightholder, if he so wishes, can register such a database with the federal executive body for intellectual property, the functions of which are performed by Rospatent (Russian Federal Service for Intellectual Property). Such registration can serve in court in the event of litigation as one of the proofs of the existence of this database. In addition, the fact of state registration of a database as an object of related rights is the basis for the

application of the provisions of Articles 1232 and 1262 of the Civil Code of the Russian Federation to it, namely: the alienation of the exclusive right to such a database under an agreement is also subject to state registration, otherwise the transfer of an exclusive right is not considered held (clause 6 of Article 1232 of the Civil Code). This requirement is due to the need to maintain the Register of Databases of the Russian Federation, which is maintained by the Federal Service for Intellectual Property, in an up-to-date state in terms of information about rightholders. The right to such a database passes at the time of state registration. The requirement for state registration does not apply to license agreements on granting the right to use a registered database.

There are also no legislative restrictions on the granting of the right to use objects of related rights in Russia. Provided by Article 1236 of the Civil Code, types of license agreements are applicable to all objects of related rights. Granting the right to use an object of related rights is possible both under the terms of a simple (not exclusive) license, and under the terms of an exclusive license (without the licensor retaining the right to issue licenses to other persons). There is no information on the provision of compulsory licenses in the Russian Federation in relation to objects of related rights (Article 1239 of the Civil Code). Since 2014, the Civil Code has been supplemented with provisions on open licenses for objects of related rights. An open license for an object of related law presupposes the conclusion of a license agreement under the terms of a simple (non-exclusive license) in a simplified manner (clause 2 of Art. 1308), to which the provisions of Art. 1286.1 Civil Code. At the same time, some experts question the possibility of extending, apart from works of science, literature and art, provisions on open licenses for other results of intellectual activity, including objects of related rights, noting that currently the subject of open licenses in the sense of Article 1286.1 of the Civil Code of the Russian Federation can only be the right to use works of literature, science or art.[8] A licensing agreement such as an open license is considered an «adhesion contract»[9]. An open license may provide for the conditions that the acceptance of such an agreement by the licensee may be expressed in the performance of implicit actions defined in this license (para 2 of clause 1 of Article 1286.1 of the Civil Code). The terms of an open license must be available for review by

[8] Kalyatin V.O. Development of a system for regulating the disposal of intellectual property rights in Russia // SPS Consultant Plus.

[9] An adhesion contract is under Russain law a contract, the conditions of which are determined by one of the parties in standard forms, in which the second participant of the agreement cannot make changes.

an indefinite number of persons (for example, the packaging of the copy, the website of the copyright holder, information accompanying the object when trying to download it to a computer), and the licensor must provide the licensor with the opportunity to familiarize the licensee with such a license prior to using the protected object. An example of such licensing agreements are «packaging licenses», known since the adoption of the Law of the Russian Federation of September 23, 1992 «On the legal protection of programs for computers and databases» (clause 3 of Article 14), where all the essential terms of the license agreement were stated on the packaging of a computer program or database, and it is considered that the user, by opening the packaging, agrees to the terms of the license.

In Article 1286.1 of the Civil Code of the Russian Federation the legislator developed the idea of "packaging licenses", providing the copyright holder with wider opportunities to conclude licensing agreements for various types of models, including the increasingly used on the Internet licensing under the terms of "Creative Commons".[10]

According to the general rule established by clause 3 of Article 423 of the Civil Code, a civil contract is assumed to be compensated, unless otherwise follows from the law, other legal acts, the content or essence of the contract. However, there is a different rule for open source licenses. In para 1 of p. 3 Article 1286.1 of the Civil Code established a rebuttable presumption of gratuitousness of such an agreement, that is, if the agreement does not provide otherwise, an open license is considered gratuitous. The scope of the powers granted to the licensee may also include the right to use the work belonging to him to create a new result of intellectual activity. Failure to indicate the territory of the permitted use of the protected object implies the possibility of its use throughout the world.

Such a license should not be considered as a waiver of the right holder from his rights, since he retains control over the use of the protected object, the right to exercise and dispose of an exclusive right and the right to prohibit the use of the object outside the granted rights. The copyright holder also has the right to apply for the protection of his rights in cases of their violation and to demand the application of protection measures in accordance with Article 1252 of the Civil Code. It may seem that certain elements concerning the procedure and conditions for the conclusion of open licenses are disclosed in Article 1233 of the Civil Code. However, as follows from para 9 of p. 5 of Article 1233, the provisions of the specified paragraph

[10] At the same time, it is necessary to make a reservation that in each particular country the possibility of such use and its limits is subject to clarification

of Article 1233 does not apply to open source licenses. Applications for providing any person with the opportunity to use free of charge the objects of related rights belonging to him on conditions determined by the rightholder and during the period specified by him differ from open licenses. The placement of the application is the basis for the rightholder's obligation to refrain from granting the right to use the corresponding result, and to a third party the right to use this result. For the copyright holder who made a statement, regardless of the use by a third party or consent to use the result of intellectual activity specified in the statement, legal consequences occur, in particular, those given in para 7 p. 5 Article 1233, as well as the impossibility of the subsequent conclusion of license agreements, on the conditions specified in the application.

In Article 1233 of the Civil Code of the Russian Federation, the legislator provided for an independent way of disposing of the exclusive right to works and objects of related rights. Some experts regard the provisions of para 5 of Article 1233 of the Civil Code as introducing a unilateral restriction by the rightholder of his exclusive right in order to expand the possibilities of using objects of copyright and related rights on the Internet.[11]

Such a statement should not be considered as a public offer of the accession agreement on the granting of the right to use on a gratuitous basis. Having made the statement provided for in para 5 of Article 1233 of the Civil Code, the copyright holder cannot provide third parties under a license agreement with the right to use the result of intellectual activity in relation to those uses that are indicated in the application. However, the wording of clause 5 of Article 1233 allows different interpretations.

During the period specified by the rightholder, any person has the right to use this work or this object of related rights on the conditions specified by the rightholder (clause 5 of Article 1233). The statement of the copyright holder is an action that is considered as a unilateral transaction, and not a legally significant message (Article 165.1 of the Civil Code). The statement is addressed to everyone who is interested in using the object specified in the statement. It should not be sent anywhere and, unlike legally significant messages, does not have specific addressees.

The statement is made by posting a message on the official website of the federal executive body on the Internet. The federal executive body responsible for the placement of the relevant applications, as well as the procedure

[11] Commentary on the part 4 of the Civil Code of Russia. E.A.Pavlova (ed.). Moscow, 2018, p. 86. (In Russ.).

and conditions for their placement, are determined by the Government of the Russian Federation. However, such a body has not yet been appointed. It seems that the statement made by posting information on the website of the federal executive body is remotely similar to the open licenses provided for objects of patent law (Article 1368 of the Civil Code). Although with regard to inventions, utility models and industrial designs, this is not a unilateral transaction, as follows from Article 1233 of the Civil Code, but on a license agreement concluded subsequently with the patent holder.

According to O.M. Kozyr, the statement provided for in para 5 of Article 1233 of the Civil Code, «is essentially a» directed «refusal of a person to exercise the right to an object belonging to him.»[12] This approach seems to be ambiguous. Such a statement should not be considered as a waiver of the exercise of the exclusive right, since such a statement does not restrict the right to use independently (the rightholder can use the results of intellectual activity on his own), to dispose outside the granted rights (the rightholder can grant the right to use under the contract in ways that do not named in the application, or on the territory not specified in the application), to prohibit unlawful use of rights, and to protect violated rights including in court (as evidenced by para 8 of clause 5 of Article 1233), etc. Perhaps it makes sense to combine the provisions of para 5 of Articles 1233 and 1286.1 into a unified legal structure that allows one to conclude licensing agreements for the granting of the right to use objects of copyright and related rights in a simplified manner. Recently, many objects of copyright and related rights are placed by copyright holders in «cloud technologies» with the provision of access to them via the Internet. There is a debate in legal doctrine as to whether the provision of access to such objects via the Internet is a use (and therefore requires the conclusion of licensing agreements) or we are talking about contracts for the provision of services, since objects are not downloaded directly to the user's computer, and therefore it is not advisable talk about reproduction as one of the ways to use the result of intellectual activity. In this regard, many questions arise regarding the legal regulation of the use of objects of intellectual activity on the Internet.

Chapter 71 of the Civil Code of the Russian Federation does not mention a pledge agreement in relation to related rights. In this regard, some researchers, for example, Yu.S. Kharitonova does not consider the objects of related rights to be those results of intellectual activity, the exclusive rights to which can be the subject of a pledge.[13] However, this is refuted, in

[12] Ibid.

[13] Agreements providing for the circulation of exclusive rights. P., 184.

particular, by the provisions of Article 1319 of the Civil Code, from which it follows that the performer can conclude a pledge agreement, the subject of which will be the exclusive right to a specific performance specified in the agreement and belonging to this performer. That is, if the object is sufficiently concretized in the contract, and the rightholder is directly the pledger, there is no reason not to conclude agreements on the pledge of the exclusive right to them with respect to the objects of related rights.

According to Ch. 23 of the Civil Code, the pledge refers to the methods of securing the fulfillment of obligations, while the pledge of the exclusive right has greater legal significance, since it is also an independent contract. A separate Article 358.1 of the Civil Code is devoted to the pledge of exclusive rights. The subject of pledge may be the exclusive right to any result of intellectual activity or means of individualization, in respect of which disposal is allowed. Neither the Civil Code nor other legislative acts of the Russian Federation provide for a prohibition on the disposal of the exclusive right in relation to objects of related rights, therefore, there are no restrictions on pledge with respect to objects of related rights. As follows from Article 358.1, a pledge of exclusive rights is possible, as well as a pledge of rights under an alienation agreement or under a license agreement. The general provisions on pledge (Articles 334-356 of the Civil Code) apply to the pledge agreement of the exclusive right to performances, phonograms and other objects of related rights. The Civil Code allows the use of a performance, phonogram and other object of related rights by the pledger, but, unless the contract provides otherwise, alienation of the exclusive right without the consent of the pledgee is not allowed.

Based on the provisions of para 5 of Article 346 of the Civil Code, which apply to agreements on the pledge of exclusive rights, the pledgee has the right to use, in the cases provided for by the agreement, the result of intellectual activity, defined as the subject of pledge, regularly submitting a report on such use to the pledger.

However, the commercial interest in such treaties in relation to related rights will not be as high as it is in relation to the exclusive right to trademarks.

3. Agreements related to the creation of the results of intellectual activity

Contracts directed or related to the creation of the results of intellectual activity include, in particular, an agreement on the creation of an audiovi-

sual work (clause 4 of Article 1317 of the Civil Code). In contracts for the creation of the results of intellectual activity, an important aspect is the conditions for the distribution of rights.

When creating an audiovisual work (for example, a feature, animation or other film), the producer enters into agreements for the creation of such a work with the scriptwriter, the author of the dialogues, the production designer, the composer, the performers, etc. When concluding such an agreement in accordance with para 4 of Article 1317 of the Civil Code, it is presumed that the performer gives his consent to the use of his performance as part of such an audiovisual work. A different approach, for example, the need to conclude an additional license agreement on the granting of the right to use the performance after the filming, should be directly stipulated by the contract between the producer and the performer. With regard to the separate use of sound or images that have been recorded in an audiovisual work, the performer's consent to their use must be also expressed in the contract.

In practice, actors conclude, for example, contracts for the participation in shooting, which include, among other things, the alienation of the exclusive right to the performance.

Inattentive study by the performers of the terms of such contracts may lead to the fact that the performer was filmed to create one audiovisual work, and his image and fragments of the performance were used in another audiovisual work, as is the case with the actress who played the role in the film «The New Year's Rate Plan (2008)». The actress did not appear in commercials before and did not give consent to the use of her performance in the advertising clip «The New Year's Rate Plan», however, frames from this film were used to create another audiovisual work.

In September 2008 an agreement was concluded between the actress and the company producing the film, according to which the actress transferred to the company the exclusive right to use the results of the services (performance of the role) in full, in any form and by any means. The contract stated that the actress ceded to the company the exclusive right to the perfomance in full. At the same time, under the contract, the company also had «the right to change the sequence of frames, change the content and title of the film, use the film (including its title) or its individual parts (any fragments of the film) to create new audiovisual and other works».[14]

[14] Resolution of the Moscow District Arbitration Court 19.01.2011 No. КГ-А40/17146-10 on the case No. A40-168251/09-26-1216 // SPS Consultant Plus.

In this regard, all the attempts of the actress to judicially recognize the exclusive related rights to use her performance in the advertising clip «The New Year's Rate Plan» and oblige the defendant to publish the decision on the violation committed were unsuccessful. The court dismissed the claim.

Objects of copyright can be created as a result of work under contracts, in particular, under an author's contract, a research contract, a state or municipal contract. The author's contract may also determine the procedure for the distribution (transfer or grant) of rights to a work that must be created under such an agreement. Since, according to the general rule (clause 3 of Article 1228 of the Civil Code), the exclusive right initially arises with the author, and the author's contract may provide for the alienation or granting of the right to use the work, the creation of which is determined by the contract.

The Civil Code provides for provisions related to contracts for ordering works of science, literature and art, as well as industrial designs (Articles 1288, 1372 of the Civil Code). However, with regard to objects of related rights, the legislator did not provide for special provisions in the Civil Code concerning type of contracts, as is the case with objects of copyright and patent rights. Can objects of related rights be created under an author's contract?

Author's contract, which is an independent type of agreements aimed at creating a result of intellectual activity, is often considered as a work agreement, since it must indicate the result of the work performed (in this case, the result of intellectual activity), recorded on a tangible medium, and indicate the main characteristics of such a result. For works of science, literature and art, the volume, type, genre, scope, name [Gavrilov E.P., 2005: 206], topic, summary, problematic issues, plot, etc. can be determined.[15]

It seems problematic to preset the exact characteristics for some objects of related rights. The customer is less interested in the process of performing the work itself. In this regard, for such objects as performance and broadcasting, which are in themselves a process, the application of the provisions of the order agreement is excluded. In relation to these objects, we can talk about the results of the provision of services.

I believe that the author's contract occupies a borderline place. It can be classified as mixed contract and contain elements of various types of contracts. Many conditions in this type of agreement are left to the discretion of the parties. However, when performing it, the personality of the per-

[15] Civil Code of the Russian Federation: Copyright. Neighboring Rights. Commentary to Chapters 69-71. P.V. Krasheninnikov (ed.). Moscow, 2014, p. 335. (In Russ.).

former is important. The subject of such an agreement can be considered the commission of certain actions that have a useful effect. Such results of intellectual activity as performances and broadcasting can be created in the process of providing services under a contract. The main goal of such agreements is not to create a protected result of activities, but to obtain a different positive effect as a result of such activities. As noted by E. Morgunova, a service is «an action that benefits the counterparty.» [Morgunova E.A., 2008: 71] With regard to objects that can be created when rendering a service, it is difficult to foresee the result in advance.

At the same time, even at the stage of pre-contractual disputes, the possibility of recording the performance, its broadcasting on the air or by cable should be discussed. For example, by concluding an agreement on the provision of musical accompaniment for a children's matinee, the performer can grant the organizer of the event (or another person) the right to record his performance and then use the recording of the performance on the terms specified in the contract.

At the same time, it is impossible to exclude the possibility of creating a database under such type of contract, which will be recognized as an object of related rights.

4. Contracts aimed at the exercise of other intellectual rights

Before talking about contracts aimed at exercising other intellectual rights, one should analyze what other intellectual rights may be applicable to the objects of related rights.

These rights include the right to receive remuneration for performance (Articles 1320 and 1295 of the Civil Code). With regard to the amount and procedure for its payment, an agreement on remuneration for performance may be concluded between the employer and the performer. Although some experts believe that in cases when it comes to official results of intellectual activity, the creator of the result of intellectual activity receives remuneration for the creation of such a result in the form of wages, which is fixed in an employment contract or civil law contract, and not in an independent (additional) agreement between the employer and the contractor.

At the same time, we do not consider it correct to attribute to other rights the right to remuneration for the free reproduction of phonograms and audiovisual works for personal purposes (Article 1245 of the Civil Code), the right to remuneration for the public performance of a phono-

gram published for commercial purposes, the right to remuneration for broadcasting on the air or by cable of a phonogram published for commercial purposes (Article 1326 of the Civil Code).

These rights are elements of the exclusive right of performers and producers of phonograms, in respect of which the Civil Code has established a restriction. I believe that treaties for the exercise of such rights should be separated into a single subgroup in the category of treaties for the exercise of intellectual rights.

Despite the fact that the remuneration is paid in favor of the rightholders, in accordance with the legislation, agreements on the payment of remuneration for public performance and broadcasting or by cable of a phonogram published for commercial purposes are concluded between users and an accredited organization for the management of related rights on a collective basis. At present, such an organization is the Russian Organization for Intellectual Property (VOIS). The exercise by the user of his right to use the result of intellectual activity in the above ways, arising from the restriction of the exclusive right of the rightholder, creates an obligation for the user to conclude an agreement with the collective management organization and pay remuneration, the same obligation to conclude an agreement arises simultaneously with the collective management organization [Valdez-Martinez E.R., 2012: 111].

Under such agreements, the user (for example, theater, cinema, cafe, restaurant, etc.) undertakes to pay remuneration for the use of phonograms published for commercial purposes. The contract determines the amount of remuneration (for example, "0.5% for each act of a performance in which a phonogram is publicly performed, from the gross fees received from ticket sales")[16], payment terms (for example, remuneration is paid "based on a certificate prepared by the user on publicly performed phonograms»)[17] and the procedure for payment of remuneration (in particular,» monthly, no later than the 20th day of the month following the reporting period «)[18].

Contracts on the payment of remuneration for the free reproduction of a phonogram for personal purposes are concluded between an organization for the collective management of copyright and related rights on a collective basis (currently such an organization is the Russian Union of

[16] Resolution of the Intellectual Property Court 31.07.2017. No A11-6529/2016 // SPS Consultant Plus.

[17] Ibid.

[18] Ibidem.

Right Holders) and manufacturers and importers of equipment and material carriers used for the reproduction of phonograms or audiovisual works for personal use.

Organizations for the collective management of copyright and related rights on a collective basis, in accordance with the powers granted to them by rightholders, may also conclude licensing agreements with users on the granting of rights transferred to the management of rightholders for the respective ways of use. At the same time, agreements on the payment of remuneration should be distinguished from licensing agreements on the granting of the right to use the result of intellectual activity, since the right to use itself is granted to users on the basis of the law, the agreement determines the amount, conditions and procedure for payment of remuneration.

However, if in relation to service results the exclusive right to it, in the absence of other regulation stipulated by the contract, belongs to the employer or the person to whom he transferred it, then when playing a phonogram for personal purposes, during public performance, broadcasting or by cable, a phonogram published for commercial purposes, the exclusive right remains with the performer or producer of phonograms (or the persons to whom it was transferred under a contract or passed in succession), and the use of the protected result is carried out as an exception or limitation of the exclusive neighboring right.

5. Agreements on the exercise of intellectual rights to joint results of intellectual activity

Often, performers are united in creative groups: musical groups, ensembles. To manage their rights, they can invite a producer, they can choose a head of the creative team from among the members of the creative team, or they can exercise their rights together and without outside help.

The participants of this group may conclude agreements on the disposal of rights to jointly created results of intellectual activity. The agreement between the members of the team of performers (Articles 1229, 1314 of the Civil Code) determines the procedure for exercising rights, distributing income from the use of joint performance. The members of the creative team can decide on the joint disposal of rights and fix it in an agreement or choose a person who will dispose of the rights on their behalf. The agreement may also specify that each member of the creative team has the right to conclude agreements on the disposal of rights to joint results (in particular, performance).

6. Contracts for the provision of services in the field of show business

Obligations to provide services in relation to objects of related rights may arise, in particular, in an agency agreement (for example, for filing an application for registering a database with the federal executive body for intellectual property), an agency agreement (the producer of the performer acts as his agent), an agreement on the transfer of powers for the management of rights and others.

Exclusive related rights can also be the object of trust management (Article 1013 of the Civil Code). Such a situation is possible when the rightholder cannot independently exercise his rights, and at the same time intends to receive remuneration from the introduction of exclusive rights to the results created by him into civil circulation, in this regard, a trust management agreement is concluded.

Trust management may also be required due to certain life circumstances, for example, when a minor performer was left without parents and guardianship was established over him, or patronage was established in relation to the performer.

It seems that in addition to the exclusive right, other intellectual rights can be transferred to trust management, for example, the right to receive remuneration for performance.

Ye. A. Sukhanov considers a trust management agreement as an independent type of a civil law conract that engenders obligations to provide services.[19]

The trustee performs both actual and legal actions in relation to the rights granted to him, acting on his own behalf, but with an indication that he is a trustee.

At the same time, the opinions of experts regarding the transfer of exclusive rights to a trustee under a trust agreement differ. According to A. Anikin, the transfer of exclusive rights under a trust agreement does not take place [Anikin A.S., 2008: 193-197], but, for example, S. Grishaev has a different opinion.[20] There are no special provisions in the Civil Code of the Russian Federation on this issue. At the same time, the Code does not also prohibit the alienation of the exclusive right and the granting of the right to

[19] Civil Law. Vol. 2. E. A. Sukhanov (ed.). Moscow, 2000, 544 p. (In Russ.).

[20] Grishaev S.P. Trust property management // SPS Consultant Plus. (In Russ.).

use under the contract by the trustee on his own behalf, if such a ban is not provided for by the trust agreement.[21]

At the same time, if we proceed from the position according to which an exclusive right is transferred to the trustee under a trust agreement or the right to use an intellectual property object is granted, then such an agreement concerning registered results of intellectual activity, in accordance with the provisions of Art. 1232 Civil Code is subject to state registration.

A trust agreement should be distinguished from an agreement with an organization for the management of copyright and related rights on a collective basis. Under an agreement with an organization for the collective management of copyright or related rights, such an organization acts and performs legal actions not only in the interests, but also on behalf of the copyright holder. Collective management organizations cannot perform actions related to the exercise of the intellectual rights of rightholders on their own behalf.

Let's also pay attention to some aspects of the agreement with cable operators. This agreement is an agreement for the provision of services for the maintenance of a collective antenna and / or the provision of communication services, concluded between cable operators and users (subscribers). As a result of the provision of such a service, the operator makes it possible to receive, on a technical device of a subscriber, a radio or television program transmitted over the air or by cable by the broadcasting organization.

Such contracts do not belong to contracts for the disposal of the exclusive right to communication over the air or by cable, since cable operators are not the original owners of the exclusive right to communication over the air or by cable. These organizations obtain the right to use a radio or television broadcast message under license agreements with broadcasting organizations. Such a service is especially in demand in large cities where there are multi-storey buildings that create interference that impede the quality reception of signals carrying radio and television broadcasts.

Conclusion

As we can see, in the creative industry, in which performers, producers of phonograms of broadcasting organizations are involved, contracts of various types are concluded: these can be both contracts for the provision

[21] Anikin A.S. (2018) Legal risks associated with the use of a trust agreement for the commercialization of intellectual property. In : Increasing the efficiency of judicial protection of rights to the results of intellectual activity and means of individualization. Moscow, 2018, pp. 192–196. (In Russ.).

of services in the field of show business, and contracts for the exercise of intellectual rights. In addition to agreements on the disposal of exclusive rights, one can note an agreement on remuneration for performance, agreements on the payment of remuneration for public performance and broadcasting or by cable of a phonogram published for commercial purposes, agreements on the exercise of intellectual rights for joint performances, an agency agreement with a producer performer, an agreement on the transfer of powers to manage the rights of related rights and others.

Contracts concerning the rights of performers, producers of phonograms and broadcasting organizations can be directly indicated in part four of the Civil Code (for example, an agreement on alienation of an exclusive right, a license agreement on the grant of an exclusive right), or contractual relations are governed by other provisions of the Civil Code (in particular, a pledge agreement, commercial concession agreement).

It should be borne in mind that the service as an action is of a utilitarian nature, and the contract for its provision is aimed at obtaining a useful effect, which can be achieved not only through the actions of a specific service provider, but also with the involvement of third parties. When exercising intellectual rights to the results of intellectual activity, including when using such results, the personality of the creator of the result and its uniqueness and irreplaceability are put forward in the first place. In this regard, when concluding contracts, it is important to clearly define its essence, since the subject and its content will depend on this.

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Integrated Healthcare Delivery and Telemedicine: Existing Legal Impediments in India

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Abstract

Technological innovation and development in the healthcare sector have cast the foundations for the growth of telemedicine. Telemedicine uses remote virtual channels to deliver healthcare services to regions in the rural and urban belts. The advantages of telemedicine include timely access to healthcare: in many cases, it would be difficult to provide timely healthcare services in the absence of telemedicine. In remote healthcare, telemedicine has been especially helpful in areas with scarce healthcare services. Telemedicine is not an autonomous service; rather, it is subject to different regulations of a complex ethical and medico-legal nature. The Constitution of India states that healthcare services are largely the responsibility of state governments as per item 6 "Public health and sanitation; hospitals and dispensaries" of the State List under Schedule 7 of the Constitution. However, the central government provides the framework for health policy and planning. In particular, the Ministry of Health and Family Welfare of India (MoHFW) is responsible for initiating the digitization of healthcare. In January 2020, the NDHB promulgated the comprehensive architectural framework of the "Federated National Health Information System." This framework is directed towards linking public and private healthcare organizations across all the value chains of primary, secondary and tertiary healthcare. Furthermore, on 25th March 2020 after the unexpected

outbreak of the COVID-19 pandemic, the Medical Council of India and the NITI Aayog released new telemedicine guidelines for registered medical practitioners to facilitate healthcare services during the complete lockdown. These guidelines set down the rules for providing medical consultations to patients using telemedicine in such areas as diagnosis, treatment and the avoidance of illness and injuries. They also govern research, evaluation and the continuing education of healthcare personnel. These guidelines have led to the empowerment of medical practitioners, yet they have also imposed various restrictions. In India, telemedicine is a nebulous concept that needs to be analyzed in the light of its prospective opportunities. This paper critically examines existing Indian collaborative approaches to digital health, the prevailing legal and ethical frameworks, and the correspondence of clinical practices to current medical guidelines. It further analyzes the steps taken by India to develop telemedical practices while balancing privacy norms, medico-legal responsibility and regulatory standards. To this end, we analyze the timeline of the development of telemedicine as well as examining the role of different policies in facilitating the promotion of telemedicine and the critical impact of technological innovation on the delivery of healthcare in rural and urban India.

Keywords

virtual healthcare, telemedicine, ethics, legal implications, privacy, patients' rights

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Introduction

As healthcare institutions grow larger and merge, healthcare services become less affected by topography, remoteness, number of patients or even institutional limitations. Thanks to technological progress, digital healthcare or e-governance in healthcare is a bourgeoning sector. Visible progress in this area includes the accessibility of health information via web sites, on-line customer support, computerized and automated analysis, collaborative health improvement programs and electronic mail exchange with medical service providers. This electronically integrated healthcare system (though often termed "e-health"[1]) is based on technological innovations in telecommunications, audial/graphic technologies and computing that affect different domains from the provision of medical information to

[1] "E-health is a broader term understood as juncture of therapeutic informatics, public health and trade, referring to healthcare services and information distributed or improved through the Internet and associated technologies." (WHO on e-Health in WHA58.28 Resolution passed at the Fifty-eighth World Health Assembly, Geneva, Switzerland, 2005)

diagnosis and treatment [Della Mea V., 2001: 1–2]. Globally, the segment of healthcare is experiencing a paradigm shift in the mode of delivery and applications of healthcare services. Healthcare has lost its restrictive sense and come to mean the overall improvement of the human being; hence, it no longer refers to an act intended to restore a lost condition. When it comes to India, the healthcare industry has not made use of the Internet as profusely as other sectors so far. The Indian healthcare system has largely conventional stakeholders who believe in one-on-one consultations and diagnosis [Lahariya C. et al., 2007: 1–7].

It is owing to the pandemic and especially to the adoption of the new telemedicine guidelines that people have begun to go for digital check-ups and diagnosis. The application of digital tools, electronic commerce and technologies in every industry is driven by consumer welfare. From this standpoint, integrated healthcare is designed as a potential goal, an area of imminent significance, that legitimizes the use of enhancement practices. The electronic form of healthcare should enable the competent transfer

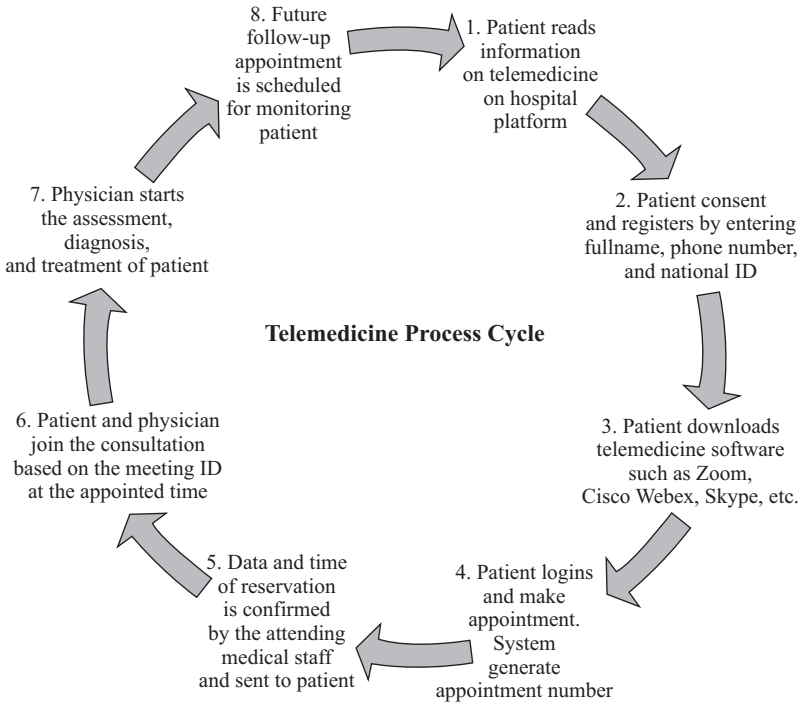

Figure 1. Telemedicine Flowchart

Source: Bokolo A. Jr. (2020) Use of telemedicine and virtual care for remote treatment in response to COVID-19 pandemic. *J Med Syst,* vol. 44, p. 132.

of healthcare services to rural and inaccessible communities and generate cost benefit transactions. In India, telemedicine is a nebulous concept that needs to be analyzed in the light of the opportunities it offers. This paper critically examines the existing Indian (national and state) collaborative approaches to digital health, the prevailing legal and ethical frameworks, and the clinical practices corresponding to current medical guidelines to determine the need for reforms or new standards. It further analyzes how India has improved telemedical practices by balancing privacy norms, medico-legal responsibility and regulatory standards.

1. Right to health and healthcare

The word "health" has many different meanings. Among these, the "right to health" encompasses all the socio-economic, ecological and legal issues that have a direct relation to health. It includes the right to healthcare, which involves safeguarding access to appropriate and affordable healthcare and, in particular, to necessary diagnostics and essential treatment.[2] The Constitution of India mostly places the responsibility for healthcare services on state governments.[3] However, the health policy and planning framework is provided by the central government. [4] The right to health is not explicitly expressed as a fundamental right in the Indian Constitution. In a broad interpretation that widens the scope of Article 21 by reading it together with the Fundamental Duties and Directive Principles, the Supreme Court has often interpreted the constitutional right to healthcare as a significant right. In Paschim Danga Khet Mazdoor Samity & Ors v. State of West Bengal, [5]the Supreme Court interpreted the state's obligation to provide qualitative healthcare in the context of the welfare state, widening the scope of Article 21 and the government's obligation to provide medical support to every person in the country. Furthermore, in Consumer Education and Research Centre & Ors v. Union of

[2] See WHO Eleventh General Programme of Work (2006-2015). This report provides a global health agenda for WHO Member States, focusing on the elements of availability, accessibility, acceptability and quality ("AAAQ").

[3] See items 6 "Public health and sanitation; hospitals and dispensaries" and 9 "Relief of the disabled and unemployable" on the State List under Schedule 7 of the Constitution.

[4] The union government using its federal powers bears the primary responsibility for respecting international obligations. The constitutional responsibility for assuring the right to health, legislation on public health, and the responsibility to assure human rights are principally upon the union legislature. See Kothari J. Social rights and the Indian constitution. 2004. 6 SCC J-31.

[5] (1981). 1 SCC 246

India,[6] the Supreme Court stated that the right to health and medical care is a fundamental right of citizens under Article 21, read with Articles 39 (e), 41, 43, and 48-A of the Indian Constitution. In Paschim Banga Khet Mazdoor Samity & Ors v. State of West Bengal & Anr, the Court addressed the matter of the suitability and obtainability of emergency health treatment and upheld that the state bears the brunt of the responsibility for assuring that primary health centers are equipped to deliver instantaneous stabilizing treatment for grave injuries and tragedies. In other judgments,[7] the Court indirectly confirmed the state's obligation to maintain standards.

Nevertheless, healthcare safeguards in India, unlike in other developed nations, are based on "supply-induced demand" that is need-based rather than "right-based." The right-based approach calls for a clear and transparent accountability mechanism in the state's decision-making, review and renovation of healthcare. It must be kept in mind that, when the affordability of treatment or medicine increases, leading to a shortage of medical practitioners, the only possible solution in the healthcare system is to rely upon technological progress. Any such transition must be effectuated by weakening the strictness of existing regulations and ignoring the conventional cultural mind-set while assuring people's rights in the process [McSherry R., Pearce P. et al., 2011: 182]. This right-based approach to technological progress in the health sector can be employed to control societal and demographic rigidities, reduce unfairness and health uncertainty, expand training, and reinforce public health scrutiny with the assistance of healthcare stakeholders for laying the foundation of public health capacity. In a speech of December 2017 UN Secretary-General Antonio Guterres stated that health is a right for all and in a new development era must have more streamlined and sustainable financing.[8]

Although Indian laws governing the healthcare industry are yet to be applied to e-health, it was necessary to promote health in a digital manner during the lockdown following the outbreak of the Covid-19 pandemic. A major step was to introduce a legal framework for telemedicine.[9]

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[6] (1995). 3 SCC 42.

[7] Vincent Panikurlangara v. Union of India. (1987). 2 SCC 165. Mahendra Pratap Singh v. State of Orissa. (1997). AIR (Ori) 37. Murli Deora v. Union of India and Ors. (2001). 8 SCC 765. Rakesh Chandra Narayan v. State of Bihar (1989). SCC Supl. (1) 644 in healthcare services with due attention to international treaties and documents.

[8] Available at: https://www.un.org/sg/en/content/sg/speeches/2017-12-14/universal-health-coverage-forum- remarks (accessed: 02.11.2020)

[9] There is a difference between telehealth and telemedicine. While telemedicine has a clinical aspect, telehealth is any use of information technology for health purposes. Al-

India lacks healthcare manpower and infrastructure, which prevents it from dealing with pressures and medicinal demands. The shortage of manpower in the public healthcare system is currently estimated at 6 hundred thousand doctors, 4 hundred thousand dental surgeons and 10 hundred thousand nursing staff [Sharma A. et al. 2013: 112–117]; [Mishra S.K., Kapoor L., Singh I.P. 2009: 568–575]. The distribution of healthcare services is also skewed. This can be attributed to the fact that approximately 75% of the healthcare infrastructure and manpower is based in urban areas where only 27% of the total population resides. The difference in the distribution of resources between rural and urban areas can be inferred from the fact that the number of doctors per 1,000 population is 0.39 in the countryside in comparison to as much as 1.33 in cities, resulting in a national average of 0.69 [Bagchi S., 2006: 82].

Such an improper distribution of healthcare resources in rural and urban settings can be corrected through telemedicine. Telemedicine can be viewed as the fastest, most effective and least expensive method of reducing this discrepancy [Achary R.V., Rai J.J., 2016: 5]. In [Achary R.V., Rai J.J., 2016: 5], the author argues that the most prominent and important advantage of telemedicine is its ability to reach rural areas of the country. Further, telemedicine possesses the potential to provide high-quality medical services to remote areas. Another advantage of telemedicine is its sustainable use of resources: it can assess the condition of a patient without actually visiting him or her [Singh R. et al., 2009: 126].

Telemedicine is the delivery of remote healthcare services to regions where the physical presence of healthcare professionals is not manageable. Such remote healthcare or telemedical services are provided to patients via information and communication technologies. This facilitates in lasting education of health care providers and thus contributes to progress in citizens' health and hence in society.

Telemedicine can be defined as the remote delivery of healthcare services through the transfer of audio, video and graphical information about a patient's health via telecommunication networks. Such information enables the healthcare provider to deliver remote consultative and diagnostic services, including planning, coordination, collaboration and education [Meher S.K. et al., 2014: 262].

Affordability and accessibility are the biggest advantages of telemedicine. It helps patients to receive fast and timely access to appropriate interventions

though both involve the application of electronic information and communication technologies to healthcare, telemedicine specifically implies long-distance patient care. (See: A. Darkins. Telemedicine and Telehealth: Principles, Policies, Performances and Pitfalls. N.Y., 2000).

and medical services which would not generally be available otherwise. India is a huge country with large geographical distances and limited healthcare resources, which makes the provision of in-person healthcare a big challenge. Thus, telemedicine is emerging as a major boon to the rural population with its very limited spending power and access to medical services.

Telemedicine helps to save resources by facilitating remote consultations, remote routine check-ups and remote prolonged continuous monitoring. This saves patients' time and money as well as reducing the burden on secondary hospitals. Further, in times of emergency such as pandemics, telemedicine protects patients and health workers from the risk of contagious infection by making physical meetings superfluous.

Telemedicine provides patients with technologies that help them to manage their medication routines easily and efficiently, leading to the better management of disease.

In recent times, different studies have been conducted on the impact of telemedicine. One study [Daly H.L., 2000: 75] has shown that telemedicine reduces healthcare expenses for patients, making healthcare services more accessible. Furthermore, examined telemedical services accorded to patients by the All India Institute of Medical Sciences (AIIMS, New Delhi), concluding that telemedicine saves time and money and is beneficial for patients from rural areas, although the perspective profits of telemedicine and ICT have not been calculated so far.

2. Telemedicine: methodology and legal issues

2.1. Telemedicine: the technology

Just as any paradigm shift, telemedicine creates both opportunities and challenges. In its literal sense, telemedicine refers to the use of technologies to provide healthcare services to patients. When distance and remoteness are issues for the proper delivery of services, information technologies are used to allow patients to consult doctors for diagnosis and treatment. Telemedicine brings together medicine and technology, using telecommunication technologies to deliver medical services [Daar J.F., Koerner S., 1997: 18]. There are two basic classes of interactive platforms available in telemedicine [Ateriya N. et al., 2018:215]:

a) Store-and-transfer (non-synchronous consultations)/store-and-forward technologies allow images to be scanned, stored, and later forwarded anywhere in the world, eliminating distance barriers

b) Human-human "real-time interaction" video conferencing (synchronous consultation) enables one-to-one consultations through the "virtual interaction" of practitioners and patients.

In telemedicine, real-time interactions can take place at the doctor-patient, doctor-doctor and/or doctor-paramedic levels. These interactions can be either telecenter-based or home-based. Here, synchronization between the central and peripheral nodes is the most important factor for the real-time interaction of individual participants.

In store-and-transfer, data is collected, saved and then conveyed from remote peripheral centers to the central node where it is examined by a specialist. For example, ECG (tele-cardiology), X-ray (tele-radiology) and similar data can be collected from the patient, stored and then transferred to the specialist for consultation. Non-synchronous consultations are specifically useful in cases which require monitoring the growth of a persistent and chronic disease such as detecting retinopathy in a diabetic patient.

By virtue of telemedicine, people in need of medical consultation, regardless of their location, can connect with healthcare professionals and receive access to healthcare. Telemedicine makes it possible to perform rapid medical intervention and support on-site, instead of conveying the patient to an alternative setting. Geographic remoteness no longer implies separation from therapeutic care. Thanks to technology, medical practitioners are able to deliver "audio, visual, and other data-sharing communications" to assist patients, reducing healthcare costs, broadening access to primary and specialty care, and providing the medical sector with an expanding market base. As a result, countries need neither to establish large health centers nor to train medical practitioners, but only to cultivate expertise and make use of technologies.

2.2. IoT and cloud services for telemedicine health practices

IoT, or Internet of Things, refers to the expansion of the capacity of the Internet beyond computers and smartphones. It has led to the creation of integrated systems comprising the Internet and digital machines. It has also engendered amalgamated digital devices with special identifiers that can be used across multiple industries.

IoT has brought about a major revolution in the domain of healthcare through the provision of continuous health monitoring services. Patients no longer need to depend solely on hospital visits for healthcare and may opt for remote medical consultation and treatment instead. Physicians can use IoT

for continuously monitoring the progress of their patients' health. Patients can take care of their health while staying at home with the assistance of advanced gadgets such as voice-activated smart speakers or order medicine through devices such as ALEXA, saving travel time and visits to the hospital.

IoT is becoming an increasingly important part of our daily lives. It is proving to be vital in the supervision of various health and medical needs. With the advent of highly popular devices such as tablets and smartphones, the medical Internet of Things (mIoT), which combines the notions of telemedicine and telehealth, is progressively gaining acceptance. These devices in combination with Internet accessibility are making advanced services available. This results in an enrichment of user knowledge and experience. Medical staff can also make more informed choices and take quicker decisions. With Internet availability, data sharing on a cloud system has also become possible. This allows multiple users, physically and geographically distant from one another, to have access to data and information anytime, anywhere.

2.3. Laws pertaining to telemedicine in India

In India, the laws pertaining to telemedicine may be categorized as in Tables 1 and 2.

Table 1

Laws pertaining to medical facilities and professions

Law
Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945[10]
Indian Medical Council Act, 1956[11]
Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002[12]
Clinical Establishments (Registration and Regulation) Act, 2010 [13]

[10] Drugs and Cosmetics Act. 1940. Drugs and Cosmetics Rules. 1945. Available at: www.cdsco.nic.in/writereaddata/2016Drugs%20and%20Cosmetics% 20Act%201940%20&%20Rules%201945.pdf.

[11] Indian Medical Council Act. 1956. Available at: www.mciindia.org/documents/theIndianMedicalCouncilActs/Complete-Act-1.pdf.

[12] Clinical Establishments (Registration and Regulation) Act 2010. Available at: www.clinicalestablishments.nic.in/WriteReadData/969.pdf.

[13] Information Technology Act. (2000). Available at: www.lawmin.nic.in/ld/P-ACT/2000/The%20Information%20Technology%20Act%202000.pdf.

Information technology services are the sources used to provide telemedicine.

Table 2

Laws pertaining to information technologies

Law
Information Technology Act, 2000 (IT Act)[14]
Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011[15]
Information Technology Rules (Intermediary Guidelines), 2011[16]
Unsolicited Commercial Communications Regulations, 2007[17]
Telecom Commercial Communication Customer Preference Regulations, 2010 [White-Williams C., Oetjen D., 2015: 4–16]

Ethical issues of telemedicine

Advances in ICT have resulted in the growing use of telemedicine in the treatment of diseases and patient care. With such advances, it is important to pay attention to the associated ethical issues as well. Thus, in order to ensure the confidentiality and safety of patient data and identify inefficiencies in the process, there exists a requirement to monitor cases of inefficiency of therapists so as to improve the quality of healthcare services. This also highlights the significance of ethical issues in telemedicine [Dombo E.A., Kays L., Weller K., 2014: 99].

The World Health Organization (WHO) defines telemedicine as an online healthcare service in which the geographical distance between the patient and the service provider matters. Furthermore, the ethical issues of telemedicine include the consideration of the benefits or losses incurred by patients in receiving telemedical services and their right to select therapy and take action against dissatisfactory services [Tarzian A. J., 2013: 3–13].

[14] Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules. 2011. Available at: www.meity.gov.in/ sites/upload_files/dit/files/GSR313E_10511(1).pdf.

[15] Information Technology (Intermediaries Guidelines) Rules. 2011. Available at: www.meity.gov.in/writereaddata/files/GSR314E_10511%281%29_0.pdf.

[16] Unsolicited Commercial Communications Regulations. 2007. Available at: www.trai.gov.in/sites/default/files/201204190608149960110Regulation5june07.pdf.

[17] Telecom Commercial Communication Customer Preference Regulations. 2010. Available at: www.nccptrai.gov.in/nccpregistry/regulation1diccndiv.pdf.

The consideration of ethical issues related to telemedical services began in the 1980s. In 2006, WHO officially commissioned the American Society for Bioethics and Humanities (ASBH) to investigate ethical issues in telemedicine. The fundamental requirement was health-related knowledge and skills [Dombo E.A., Kays L., Weller K., 2014: 111]. In addition, guidelines for telemedicine were developed to streamline the process further. These guidelines facilitated the proper management of telemedical services and the assurance of their stability, regularity and safety. These guidelines aim to improve the quality of telemedical services.

Today, the Internet is used by 87% of adults. The rate of receiving online health-related information has increased by 72%. This has enhanced the role of ethical issues in telemedicine, pushing stakeholders to improve the quality of healthcare services [Parsons T. D., 2016: 99–101]. This is further compounded by the fact that the use of technologies such as Internet, email, and smartphones creates a number of ethical issues in telemedicine [Langarizadeh M. et al., 2017: 351]. For example, ethical rules and regulations are required to ensure the confidentiality of patient information. In [Agarwal N. et al., 2020: 90], the author reviews and classifies the available literature on ethical issues in telemedicine.

Role of telemedicine in disasters and pandemics

Pandemics and disasters hamper the trials in giving healthcare. It is not guaranteed that telemedicine can successfully work at all times. It can be suitable in situations when medical practitioners are capable of managing and evaluating their patients. In telemedicine, visits and consultations can be booked without the staff coming in contact with viruses/infections at a time of epidemic upsurge. Telemedicine also eliminates the risk of being exposed to other communicable diseases for all patients and medical practitioners. The exposure of healthcare workers can be avoided through the use of telemedicine to screen patients remotely. Telemedicine can also improve the accessibility of medical practitioners in remote areas. Hence, during the current COVID-19 pandemic, health systems with advanced telemedicine systems are able to ensure that patients infected by the virus can quickly get the care they need. A recent paper on telemedicine [Mishra S.K., Singh I.P., Chand R.D., 2012: 151–163] studies the role played by telemedicine in the ongoing COVID-19 situation in India. Focusing on the Telemedicine Guidelines of March 2020 of the Medical Council of India, the researchers discuss the role of telemedicine in fighting the pandemic. The work significant to telemedicine and its applications are studied and summarized.

Telehealth is appropriate for situations where medical practitioners are available to consult patients remotely. State licensing, payment and regulatory structures, program implementation, credentialing across hospitals, etc. all take time to implement, but systems with advanced telemedicine systems are in a good position to guarantee that Covid-19 patients obtain the care they need. Thus, in the present scenario, the use of telemedicine may be the most appropriate solution.

3. Policy-based analysis

The government is striving to incorporate telemedicine into the country's healthcare system and make it an integral part of the latter. The Department of Information Technology has laid the foundations by creating guidelines to guarantee the inter-operability [LeRouge C., Garfield M.J., 2013: 6472–6484] of telemedicine as a standard practice. A comprehensive regulatory framework should be developed to understand several diverse significant pointers which would help stakeholders to understand their roles and responsibilities in a better way. With the help of telemedicine, healthcare services can be easily delivered to different places. However, the increasing application of telemedicine can also lead to the emergence of different legal and ethical issues [Balarajan Y., Selvaraj S., Subramanian S.V., 2011: 505–515]. It should be obligatory for the main parties involved, including patients and doctors, to have a clear and precise understanding of their rights. Their role expectations and duties in this new framework should also be well defined. For example, the risks of using telemedicine include the exposure of patients' confidential information such as financial and medical data. Stringent rules should be elaborated to make discretion compulsory so as to reduce concerns about the exposure of private information. Furthermore, patients can use telemedicine to receive treatment from several healthcare practitioners residing in different places, evoking controversy about liability for the patient's treatment. This can result in doctors and health workers being unclear and hesitant about their responsibilities, obligations and legal duties.

The solid financial benefits of telemedicine from the patient's viewpoint include saving travel time and money by receiving treatment at home. However, the ROIs from the healthcare provider's perspective are unspecified and uncertain. Hence, many telemedicine initiatives are implemented as "concept projects" by state enterprises or as public private partnerships (PPP). These enterprises are mainly dependent on government funding for money and hence do not strive for financial viability. By portraying

telemedicine as a vital part of the healthcare environment and endorsing the vigorous involvement of the private sector, many policy initiatives play a key role in making telemedicine projects financially viable. This is explicitly authoritative as healthcare is generally delivered by private businesses or hospitals across India [Dasgupta A., Deb S., 2008: 3-8].

4. Literature review

Table 3

Literature Review of Previous Studies in Telemedicine

Title of publication	Type, Description
"Telemedicine: A new horizon in public health in India" [Ganapathy K., Ravindra A., 2009: 576–585]	Review
"Telemedicine in India: The Apollo story." [Bhaskaranarayana A., Satyamurthy L.S., Remilla M.L., 2009: 586–591]	Review, discusses the role of ATNF (Apollo Telemedicine Networking Foundation) in the growth and development of telemedicine in South Asia.
"Telemedicine in India: Current scenario and the future" [Bagchi S., 2006: 82]	This paper discusses the role played by the Indian Space Research Organization, numerous government agencies, Department of Information Technology and Ministry of Health & Family Welfare (MOH&FW), state governments, and leading medical and technical institutions of India in the deployment of telemedicine initiatives throughout the country
"Indian Space Research Organization and telemedicine in India" [Ganapathy K., 2002: 388–394]	This article discusses the role played by ISRO in the enactment of various measures required for the deployment of telemedicine initiatives in India. It examines the ISRO's approach, the various stakeholders involved at different levels, and future prospects.
"Telemedicine and neurosciences in developing countries" [Sood S.P. et al., 2007: 257–268]	Telemedicine and neurosciences: the numerous implications of developing technologies for providing neurosurgical care to rural and urban areas of India as well as other countries.

Title of publication	Type, Description
"Differences in public and private sector adoption of telemedicine: Indian case study for sectoral adoption" [Brindha G., 2013: sup. 5]	Differences in the adoption of telemedicine by the public and the private sectors in India
"Emerging trends of telemedicine in India" [Pal A. et al., 2005: 59–65]	Discusses the demand, challenges, and procedures of telemedicine
Telemedicine diffusion in a developing country: The case of India (March 2004) [Chandwani R.K., Dwivedi Y.K., 2015: 393–400]	Potential of telemedicine development and diffusion in India
"Telemedicine in India: Current state, challenges and opportunities" [Chellaiyan V.G. et al., 2019: 1872]	Scope, challenges for diffusion and prevailing scenario of telemedicine in India
"Telemedicine in India: Where do we stand?" [Sood S.P., Tech M., 2004: 29–32]	Position of Indian telemedicine initiatives
"Implementing telemedicine technology: Lessons from India" [Ghosh A., Gupta R., Misra A., 2020: 273–276]	Discussion of a pilot telemedicine scheme in India. Analysis and insight into its strengths and shortcomings
"Telemedicine for diabetes care in India during the COVID19 pandemic and national lockdown period: Guidelines for physicians, diabetes & metabolic syndrome" [Sangal A.K. et al., 2004: 149–151]	The paper briefly discusses suggestions and guidelines pertaining to the role of telemedicine for patients with diabetes, along with its utility and limitations.
"Communication satellite-based network for telemedicine in India" [Ray S., Sharma P., Kustwar R.K., 2017: 156–172]	The paper discusses the application of the communication satellite network to telemedicine in India

The basic resource prerequisites for telemedicine are human capital and technological matters. To make an efficient medical information network, technologies must assure the precise transmission of information with minimal losses in recording, loading and delivering information. The insufficient penetration of the Internet is a limitation that must be solved to permit the forwarding and storing of high-resolution videos. To guarantee effectiveness, the technological framework must study cost effectiveness and affordability. During the preliminary phase, it is vital to experiment with telemedicine mediations for a particular type of disease to find acceptable solutions to issues such as showing diabetic retinopathy through a fundus camera and identifying affordable versions of the technology. Such problems as consistent power supply and appropriate hardware must also be overcome to confirm technology dependability. Indian doctors are considerably burdened with patients, which is confirmed by the low doctor to population ratio. Involving doctors in healthcare delivery through telemedicine requires overt methods for making tele-consultation operative and efficient. Additionally, paramedical staff provides the connection between doctors residing in cities and patients in villages. To reduce the shortage of healthcare personnel and increase the number of employees who are familiar with telemedicine, telemedicine training must be offered. It is key to improving the telemedicine coverage of the village population.

Telemedicine mediations are limited to a particular structure of medicine. The community has to be included in the delivery flowchart process as it is the most important component to increase the tolerability of telemedicine. ASHA (Accredited Social Health Activist) played an important role in the plan of NRHM (National Rural Health Mission) by endorsing the connection between the community and the formal health framework. Disabling the sociocultural obstacles and adopting telemedicine in rural areas may well depend on the use of telemedicine in the first stage of treatment such as primary care. The use of telemedicine in primary care has been insufficient so far. To use telemedicine in primary care, one needs to take a bottom-up approach starting from the rural population, considering their requirements, understanding the socio-technical framework for deploying telemedicine and involving native thought leaders. Moreover, the strategy and processes should be based on information sharing, framework practicability and the needs of villagers.

5. Applications of telemedicine

5.1. Telehealth

Telehealth is used for endorsing and providing healthcare services across large distances. It can be classified into tele-consultation and tele-follow-up.

Telehealth offers many ways of delivery, including "video consultation, transferring reports and images, creating portals for patients (e-health), monitoring vital signs, frequent medical instruction, consumer-focused wireless frameworks and nursing call-centers," text messaging, e-mail, surgical training and remote data capture.

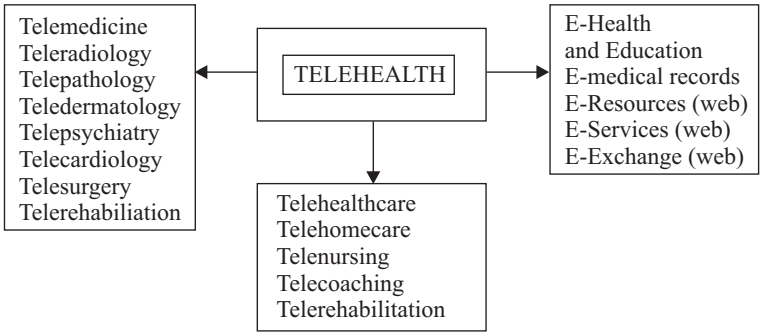

Figure 2. Telehealth flow chart

Source: http://newtel.vn/en/difference-between-telemedicine-and-telehealth/

5.2. Tele-education

Tele-education can be defined as the process of providing distance education, whether regulated or unregulated, via ICT for a flexible, interactive and accessible learning experience for the student. Telemedicine and e-healthcare services have been used competently and considerately to deal with the consequences of natural and manmade tragedies and disasters. Many studies have shown the effectiveness of telemedicine in dealing with disasters, especially in remote areas marked by a shortage of doctors and other healthcare services.

5.3. Tele home healthcare

Telemedicine technologies are vital for providing healthcare at home for patients who are aged or underserved, cannot leave their homes or have chronic illnesses. It allows healthcare specialists to observe patients from a distant central station. Distant home-based monitoring of patients is efficient, rapid, inexpensive and time-saving. Virtual interactions in telehealth home care improve the quality of home healthcare at a lower cost, increase patient satisfaction, and expand the access of healthcare professionals and patients to more sophisticated and expensive types of care. The vital functions of patients may be observed whenever required through ICT.

6. Challenges of telemedicine

In India, the biggest challenge to tackle at the policy level is to promote telemedicine and turn it into an essential component of the healthcare delivery system. [LeRouge C., Garfield M. J., 2013: 6472–6484] discusses some initiatives taken at the policy level such as the participation of Department of Information Technology (DIT) in the process of creating guidelines for the regularization of the telemedicine infrastructure to assure the operation of telemedicine at different levels. In addition, attention must be paid to many other important aspects of telemedicine. This should require the elaboration of a complete governing framework that will allow stakeholders to understand their responsibilities and liabilities.

As the operation of telemedicine increases and it is applied across varied geographies to deliver healthcare and share essential medical information, numerous new legal and ethical issues arise. For the proper use and implementation of telemedicine, the chief stakeholders, i.e., patients and doctors, will have to understand their role, duties and rights in the utilization of telemedicine. For example, if used improperly, telemedicine has the potential to threaten the confidentiality and secrecy of critical medical and economic information of patients. Thus, specific guidelines are required for assuring adequate provisions for the preservation of the confidentiality of patient data to reduce patient concerns.

Another scenario that can affect stakeholders is the treatment of a single patient by several doctors and healthcare professionals across multiple geographies, which can cause a conflict of ownership and accountability for the patient's treatment plan. Under such circumstances, doctors and health workers can be uncertain of their lawful accountability. According to some authors [Andriola M., 2019: 13] the number of legal suits against medical practitioners and doctors is increasing. Therefore, policy makers should elaborate guidelines and policies that facilitate the incorporation of telemedicine into the bigger healthcare delivery system.

As far as the economic advantages of telemedicine are concerned, patients are definitely receiving benefits such as saving on costs for travelling to urban areas for treatment. On the other hand, the returns on the investments of healthcare providers are highly uncertain. As a result, the government is organizing telemedicine interventions as "concept projects" or PPPs [LeRouge C., Garfield M. J., 2013: 6472]. Telemedicine projects normally receive government grants, as a result of which little consideration is paid to their financial viability.

For telemedicine to become an integral part of the Indian healthcare sector and for the active participation of the private sector in telemedicine, several policy initiatives must be taken. Such initiatives should be financially feasible. Furthermore, the active participation of the private sector in telemedicine is required, as the private sector plays the leading role in healthcare delivery across rural and urban areas [Dasgupta A., Deb S., 2008: 3–8].

The two basic resources required for telemedicine are people and technologies. For telemedicine to emerge as an operational technology in the field of healthcare, it must operate in an error-free manner, assuring negligible losses during the collection, storage and transfer of information. The availability of network infrastructure should be properly managed, as it is one of the major challenges in the field of telemedicine according to [LeRouge C., Garfield M. J., 2013: 6484]. This is due to the fact that good broadband connections are required for managing the demand for video and store-and-forward services. In addition, technologies should be designed to assure cost-efficiency and affordability.

While telemedicine is still at the pilot stage, it should be applied to a specific disease so as to test solutions and assess minor problems before being used for a wide range of diseases in a cost-effective manner. For example, the fundus camera can be used both for diabetic retinopathy and for image-based diagnoses of many illnesses of the teeth, skin, etc. Such an approach can share expenses between several specialties and improve the cost effectiveness of the technology. It is also important to focus on the challenges of reliable power supplies and suitable hardware.

India is experiencing a huge shortage of doctors, making existing specialists overloaded with work. Telemedicine can provide an effective solution to this problem. However, it needs explicit strategies to be workable. The emphasis on explicit diseases can significantly limit the scope of judgmental problem-solving and decision-making among doctors, greatly reducing their workload.

Telemedicine can also overcome the widespread shortage of paramedical personnel and the deficiency of staff training, which shows the importance of extending telemedicine to villages.

The predominant recognized norms that regulate the healthcare consumption of the population can be ascribed to socio-cultural barriers. In the case of primary care in the context of developing countries, alternative systems of medicine provided by native doctors are the typical choice available to patients. However, telemedicine is constrained to the official

system of medicine. In order to increase the adoption level of an intervention, it is important to involve the community in the process of healthcare delivery, which is an important design element for acceptability. In the same direction, ASHA (Accredited Social Health Activist) has acted as the backbone of the design of the NRHM program by safeguarding the relation between the formal health system and the community.

The integration of telemedicine into primary healthcare should play the biggest role in reducing socio-cultural barriers in rural areas to enhance telemedicine adoption. The initiative of telemedicine discussed in the previous sections has mostly focused on the delivery of expert advice from the central nodes to the periphery. This has subsequently contributed to secondary and tertiary healthcare delivery as well. As far as the design of technology, processes and systems is concerned, a "top-down" method is used. While telemedicine has a huge potential in the healthcare industry, it is unfortunately underutilized today.

In contrast, telemedicine for primary care requires a "bottom-up" method. This can be initiated at the community level by measuring the requirements of the community, the participation of local thought leaders, etc. Furthermore, the implementation of a bottom-up approach in telemedicine will promote efficiency and a higher adoption rate at the secondary and tertiary levels as well. One should design technologies, systems and processes for primary-care telemedicine only after understanding the predominant socio-technical systems in communities.

7. Conclusion

The Indian government is dedicated to providing equal and non-discriminatory access to high-quality healthcare to all citizens. The inclusivity of the health system can be improved with the help of digital health. Thus, turning telemedicine into a routine method of the healthcare system will reduce unfairness and hurdles to healthcare access, despite all the hesitations voiced about the new technology.

Early telemedicine ventures in the country were backed by government funding. Such ventures were either introduced into the public health framework or implemented as PPPs. Telemedicine needs the vigorous participation of private companies on a continual basis to become an essential part of the healthcare framework in the country. This requires the involvement of all the participants, including policymakers, doctors, specialists, paramedical staff, coordinating and technical staff, and the rural community from the initial planning stage on.

Telemedicine leads to an overall decrease in healthcare costs by assuring the fast delivery of healthcare at a minimal price. As technology develops to enable quicker and more effective communication, the logistical hurdles that once hindered the diffusion of telemedicine will disappear. Nevertheless, the legal system must also catch up with the process.

Telemedicine encroaches upon the conventional legal framework in three ways: (a) in the regulation of medical practice, (b) in dispute resolution of negligence cases and (c) in the lack of legal safeguards for the confidentiality of patient information. The downsides of telemedicine are the lack of a standardized arrangement for interaction. The Medical Council of India (MCI) was created by the Indian Medical Council Act in 1956. In 2019, the National Medical Commission Act replaced the MCI by the National Medical Commission (NMC). Other than the NMC, there exist the Indian Nursing Council, the Dental Council of India, the Rehabilitation Council of India and the Pharmacy Council of India. The NMC Act sets out the regulatory and advisory role of the NMC and the Medical Advisory Council under the aegis of the Ministry of Health and Family Welfare (MoHFW). Through this Act, the Ministry not only frames strategies for regulating medical institutions and medical professionals but also maintains minimum standards for medical education. Furthermore, medical devices are governed in India by the Drugs and Cosmetics Act (1940) along with the Medical Device Rules (2017), which cover a wide range of drugs, therapeutic substances, diagnostics and medical devices. The Central Drug Standards Control Organization (CDSCO) serves as a regulatory body for pharmaceuticals and medical devices. These regulatory frameworks are consistent with pertinent technical recommendations from WHO. Although MoHFW issued the Telemedicine Practice Guidelines as Appendix 5 to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations (2002) in tandem with NITI Aayog (National Institution for Transforming India), there still remain lot of loopholes. These are mere guidelines that lack enforceability. The notorious 2018 Mumbai High Court judgment in Deepa Sanjeev Pawaskar v. State of Maharashtra highlighted the perils of telemedical practice by ruling that a medical practitioner was guilty of medical negligence under Section 304A of IPC by causing death due to negligence.[18]In the conventional approach, medical negligence can be established by proving the existence of the following elements: a duty to be performed by a medical practitioner in conformity with certain standards; a breach of these standards of care; (3) an

[18] See SCC OnLine Bom 1841 Order of 25 July 2018.

injury; and (4) a causal relationship between the breach of care and the patient's injury. However, when the judgment states "prescription without physical diagnosis and henceforth resulting in the death of the patient amounts to criminal negligence on the part of the doctors,"[19] the question pertains to telemedicine. What checklists can assure a reasonable degree of care and skill? As telemedicine makes use of technical means, what precautions can be taken by doctors and patients against errors taking place due to a breakdown in communication because of technical glitches? These and other questions are ambiguous. In other countries, the term "telemedicine entity" is properly defined so as to set down the liability of stakeholders who provide telemedical services. [20] Conventional structures should be contrasted with telemedicine's ability to provide diagnoses for inaccessible patients in India.

Moreover, the guidelines state that only doctors enrolled in the State Medical Register or the Indian Medical Register can practice medicine. [21] However, there is no mention of any authority who crosschecks the names of medical practitioners in telemedical services. Conversely, how can a medical practitioner be sure of the patient's identity and his or her medical history when entering into a virtual office via video-conferencing? Licensing as a regulatory element serves the vital objective of guaranteeing that medical practitioners meet educational and clinical capability criteria. This helps to safeguard the public from incompetent or unskilled practitioners. Licensing is significant for enforcing medical standards, as the licenses of unfit practitioners can be withdrawn. However, the incoherent telemedicine system currently prevailing in India prevents the distribution of information amid licensing authorities. There is no checklist for verifying whether a practitioner of telemedicine is licensed or whether his license has been suspended or revoked.

Let us consider a recent case regarding a prescription that was shared by many users in the social media. The prescription was entitled "On fighting coronavirus as per Indian Council of Medical Research (ICMR) guidelines" and posted by a certain "Dr Raj Kamal Agarwal, Senior Consultant at the Department of Anesthesiology of Sir Ganga Ram Hospital, New Delhi." It recommended taking "HCQ, 400 mg" once a week along with vitamin C

[19] Ibid. Para 7.

[20] See the Electronic Code of Federal Regulations (e-CFR) — the web version of the Code of Federal Regulations (CFR) published in the Federal Register by the departments and agencies of the US Federal Government.

[21] See the Gazette Notification for Telemedicine Practice Guidelines. Available at: https://www.mohfw.gov.in/pdf/Telemedicine.pdf. (accessed: 15.11.2020)

to gain immunity against the pandemic. This matter came to the attention of Ganga Ram Hospital officials, who filed a mal-information case. On due verification, it was found that the ICMR had never issued such a guideline for taking HCQ pills. If such prescriptions can make rounds during the pandemic, what can happen with the audio or video clips that are regularly used on telemedical services? This again poses the question of introducing safeguards into current regulations.

Another concern pertains to "informed consent," which is a vital prerequisite for treating a patient in medico-legal jurisprudence. Essential communication between patients and medical practitioners in the course of medical treatment is fundamentally embodied in the legal dogma of "informed consent." In accordance with professional standards, there exists the practice of direct diagnosis, in which medical practitioners converse personally with patients to gain the necessary information. The patient's consent should go hand in hand with the trust he or she places in the medical practitioner's respect of the confidentiality of their dialogue [Wibberley L.E. , 2017:885]. In telemedicine, the biggest accountability concerns relate to the establishment of the physician-patient relation, the applicable standard of care, and informed consent. With no clear explanation provided in the MoHFW Telemedicine Practice Guidelines and no case precedents, it remains uncertain whether the confidentiality standards used in face-to-face consultations remain suitable within the telemedicine setting, particularly in view of the advanced technologies involved. There are many researchers who opine that the new technologies risk depriving medical professionals of information that they would obtain during an in-person check-up and possibly lead to mistreatment [Lee T. H., 2010: 69]. Such risks may affect every stage of medical care, including examination, diagnosis and treatment. The legal doctrine of care in negligence cases is the "reasonable person standard test" — i.e., what a reasonable person would do if he faces the same set of circumstances as the defendant.[22] Given that telemedical services considerably alter traditional face-to-face consultations, one must examine whether the rules for proving the standard of care should be changed. Another issue that needs to be resolved regards the "vicarious liability" principle under the Common Law. Civil law recognizes the liability of the employer for an employee who makes errors in the course of his/her employment. The question remains open whether a hospital is responsible for telemedical care provided by a practitioner associated with the institution [Stanberry B., 2006: 175].

[22] Jacob Mathew vs. State of Punjab & Anr. (2005) 6 SCC 1

8. Future directions

As an innovative model for processing medical data, telemedicine is governed by different legal frameworks dealing with medical regulation, data protection, data sharing, communication technologies and further aspects of scientific research. Hence it involves aspects of cyber law, especially under the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules (2011), the Information Technology (Intermediaries Guidelines) Rules (2011), the Telecom Unsolicited Commercial Communications Regulations (2007) and the Telecom Commercial Communication Customer Preference Regulations (2010). However, issues such as the leakage of patient data to third parties, the mode of storing such data, subsequent detrimental effects on data, etc. are not mentioned in the MoHFW governmental guidelines. Such administrative aspects of telemedical services are very important, because they entail elements related to transmitting and storing session footage and patient data, maintaining and updating software, capacity building, infrastructure, and training programs for healthcare workers and technicians.

In addition, it is important to understand the roles of different stakeholders of this service. These stakeholders include not only patients and doctors but also telemedicine technicians, paramedical service providers, teleservice providers, the pharma industry and insurance companies. The principal issue pertains to the protection of patient privacy with the digitization of medical records. In the telemedicine scenario, providers must meet the challenge of guaranteeing the adequate protection of the privacy of audio and video communications. Data privacy in healthcare must strike a balance between utility and security. MoHFW guidelines do not identify the party that should ultimately be held for a security breach. Telemedicine involves a continual interchange of information among the patient and the service provider. The personal information of patients, be it their medical history or physical disorders or physiological conditions, have to be categorized as sensitive personal data in order to give patients an opportunity for legal recourse. With the Personal Data Protection Bill (2019) pending before parliament, safeguarding patients' data is a challenge that India needs to overcome. The potential use of cryptography, password-protected attachments, etc. has been proposed by jurists in other countries to assure information privacy.

Because telemedicine is a relatively new field that is indispensable during the current pandemic, patients need to gain a proper understanding of its advantages and disadvantages. As a result, the elaboration of its frame-

work should receive priority attention. In the absence of personal data protection legislation in India today, guidelines for telemedicine, including its clinical, technical and operational aspects, need to be drafted and then approved by the National Medical Commission (NMC). What are the limitations of telemedical services? What are its dos and don'ts? What happens if one or more avenues of communication/examination are lost? Where shall the patient's records be kept? These and other questions can be answered only through the development of an NMC framework that would regulate all telemedicine consultations.

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International Law Regulation on Access to Health Technologies

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Abstract

Over the past decades, the number of system challenges in health protection has rapidly increased, impacting every country, regardless of the economic well-being level. The situation is mainly driven by socio-demographic shocks, geopolitical instability, as well as the lack of a systematic approach to the development of legal regulation of the health sector at the international and national level. Health technologies are fundamental to providing health care, social care, and responding to natural and deliberate emergencies. Access to healthcare technologies is regulated by various branches of international law, which determines the complexity of this process, as well as the need to form special international legal mechanisms to ensure systematic counteraction to threats in the field of health protection, including emergencies. This article presents analysis of the access to health technologies role in rethinking the concept of human security at the international level, as well as in the framework of national security strategies. The author consistently examines the main directions for the development of health technologies transfer regulation, including the protection of the IP rights, the formation of global partnerships in the field of procurement, as well as the harmonization of legal regulation within the framework of regional economic integration initiatives. Special attention in the article is paid to the analysis of the main international regulation for data transfer and access to scientific knowledge necessary for health technologies transfer, as well as the assessment of national regulation. Based on the conducted analysis, the author formulates proposals for improving the international legal mechanisms regulating access to health technologies.

Keywords

international law, security, right to health, health technologies, technology transfer, harmonization, access.

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From the moment the first International Sanitary Conferences were held in the early 19th century and the establishment of the International Office of Public Hygiene (OIHP) until the end of the first decades of the existence of the World Health Organization (WHO), the main focus of international cooperation and acts of international law in the field of health has been countering the spread of infectious diseases. Under the influence of technological advances that made it possible to curb the spread of infectious diseases, there was a shift in the priorities of international cooperation to issues related to non-communicable diseases (oncology, diabetes mellitus, cardiovascular diseases, hereinafter — NCDs) and the provision of universal health coverage.

NCD therapy involves the use of a variety of health technologies. For example, medical devices to control the course of the disease, drugs to curb the development of the disease, etc. The growing need for the use of health technologies forms a vicious circle, increasing the economic burden on health systems and, as a result, limiting access to health technologies, especially for vulnerable groups of the population, leading to disability, disability, which ultimately leads to a reduction in national income. The long-term socio-economic consequences for each state due to the spread of NCDs determined the attention to this problem not only on the part of WHO, but also became the basis for high-level meetings at the UN site in 2011, 2014 and 2018.

It should be noted that, despite significant advances in the development of antibiotics and an increase in the rate of vaccination, infectious diseases are becoming an increasing threat. In various regions of the world, more than 30 outbreaks of infectious diseases were recorded, which were an indicator of the imperfection of the legal mechanisms for controlling their spread, formed over the previous century [Mukherjee S., 2017: 459–467]. The main reasons for this situation, along with systematic problems in the activities of WHO and other international organizations, was the lack of comprehensive mechanisms for access to health technologies.

1. Defining term “health technologies”

The term “technology” comes from the Greek “techne” which means a skill, art, craft, or method used to make a certain object, and “logos” which stands for “thought”. Guided by the UN Secretary General’s Report, technologies represent the main factor in ensuring human well-being and state development, allowing them to create new jobs, increase labor productivity, reduce the cost of goods and services, and expand the availability of medical and social assistance[Impact of rapid technological change on sustainable development, 2019: 17].

Despite the presence of the first mentions of the application of health technologies in the 7th century BC, to date, among the documents of international organizations and scientific research, a unified definition of the concept of health care technology has not been formulated. According to one of the first attempts to formulate a definition of this concept in Resolution WHO 60.20, health technology should be understood as the application of systematized knowledge and skills in the format of various medical applications (medicines, medical devices, etc.) aimed at improving the quality of life and solving global health problems.

It should be noted that after a decade, under the influence of rapid technological progress, the WHO definition no longer fully reflects the entire range of solutions actively implemented in the system of medical and social assistance. In particular, this thesis is confirmed in his speech by the WHO Director-General, who emphasizes the growing role of gene editing technologies, robotic surgery, 3-D printing, artificial intelligence (AI) for health systems.[1] In addition, in the context of an increase in the rate of disability of the population and the regulation of social protection issues in the activities of the International Labour Organisation and other international organizations, it is necessary to mention assistive technologies aimed at improving the quality of life and the integration of persons with disabilities into social processes. [Rehabilitation in health systems, 2021: 35].

It is also necessary to mention the approaches to the definition of “health technology” at the national level, where this term is not enshrined in domestic law, but at the same time is presented in official documents prepared by authorized national institutions. Center for Healthcare Quality Assessment and Control of the Ministry of Health of the Ministry of

[1] WHO, WIPO, WTO Joint Technical Symposium on Cutting-Edge Health Technologies: Opportunities and Challenges. Available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_20.pdf (accessed: 22.02.2021)

Health of the Russian Federation has defined health technologies as any intervention that can be used to promote health, prevention, diagnosis, treatment of illness, rehabilitation of patients or provision of care, including drugs, medical devices, procedures and organizational systems.[2] The National Information Center on Health Services Research & Health Care Technology (NICHSR) of the United States defined health technologies as the practical application of knowledge to improve or maintain the health of humans and the population, formulating three ways of describing health technologies based on their physical nature (medical devices, software, pharmaceuticals). means, etc.), purposes of application (prevention, rehabilitation, diagnostics, etc.) and stages of implementation into practice (experimental, investigated, conceptual, etc.).[3]

2. Current state of world health technologies market

Under the influence of the technological process, accompanied by an increase in the life expectancy of the population and an increase in the need for medical and social assistance, healthcare technologies are one of the most dynamically developing world markets. By 2025, the pharmaceutical segment of the healthcare technology market alone will reach $1.6 trillion, excluding the cost of vaccination against COVID-19, which will amount to $ 157 billion. It should be noted, however, that the COVID-19 pandemic has led to an increase in the expected size of the pharmaceutical market by $ 88 billion. The main sources of growth in the pharmaceutical market in the coming years will be drugs for the treatment of cancer and immunological diseases. In the next 5 years, 100 new drugs in the oncology segment are expected to be registered, with global costs reaching $ 260 billion by 2025.[4] Special attention should be paid to research in the development of gene-cell technologies, which marked the era of personalized medicine and suggests new approaches to the provi-

[2] Center for Healthcare Quality Assessment and Control of the Ministry of Health of the Russian Federation Available at: URL: https://rosmedex.ru/hta/ (accessed: 22.02.2021)

[3] National Information Center on Health Services Research and Health Care Technology (NICHSR). Available at: https://www.nlm.nih.gov/nichsr/hta101/ta10104.html (accessed: 22.02.2021)

[4] Global Medicine Spending and Usage Trends: Outlook to 2025. IQVIA 2021. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-medicine-spending-and-usage-trends-outlook-for-2025/iqvia-institute-global-medicines-and-usage-trends-to-2025-0421-forweb.pdf (accessed: 02.09.2021)

sion of medical care. In 2020, research in the field of gene and cell products accounted for 12% of the total number of clinical trials.[5] It should be noted that the predominant source of funding for such research is not pharmaceutical manufacturers, but government research institutes and venture funds. Thus, the volume of funding for research of gene and cell technologies by the US Government is more than 550 million US dollars annually.[6] In 2020, under the influence of the COVID-19 pandemic, a rapid "digitalization" of the medical care system took place, which had a significant impact on the healthcare technology market, and also generated the need to improve the legal regulation of this area. To date, the number of various mobile applications in the healthcare sector has exceeded 350 thousand, of which 90 thousand were launched in 2020 [Digital Health Trends 2021: 2021]. The digital segment of healthcare technologies is characterized by significant investment attractiveness. In 2020, $24 billion was invested in the development of digital solutions for the healthcare sector.

In the context of the rapid increase in the growth rates of investment in research and development, as well as the emergence of new health technologies, there is a growing need for the formation of sustainable international legal mechanisms that ensure equitable access to such technologies for all groups of the population.

3. Access to health technologies on the agenda of international bodies

Taking into account the complex nature of the regulation of using health technologies, each of the stages of which has a significant impact on the accessibility among the population, it should be noted that this issue is covered not only by WHO, but also by other UN specialized agencies, as well as by other participants in international relations in the field health protection.

For the first time, access to health technologies as an important element of health protection and the concept of human security was identified in the framework of the UNDP report "New dimensions of human security" 1994. However, the full importance of access to health technologies in the

[5] Available at: https://www.mckinsey.com/industries/life-sciences/our-insights/biopharma-portfolio-strategy-in-the-era-of-cell-and-gene-therapy (accessed: 02.09.2021)

[6] National Center for Advancing Translational Sciences. Past budgets. Available at: https://ncats.nih.gov/about/center/budget/past (accessed: 02.09.2021)

international agenda was formulated in the framework of the Millennium Development Goals (MDGs) approved by the UN General Assembly in 2000. In particular, the achievement of three of the eight main goals, such as combating HIV / AIDS, malaria and other diseases, improving maternal health and reducing child mortality, ensuring the availability of essential medicines in developing countries, directly depend the availability of healthcare technologies. Further, within the framework of the Sustainable Development Goals (SDGs), which were also approved by the UNGA in 2015 as the successors of the MDGs, access to health technologies was identified as one of the objectives of SDG 3 "Ensuring healthy lifestyles and promoting well-being for all at all age".

Special attention in the international agenda is paid to ensuring control over the use of antibiotics both in medicine and in agriculture. The mandate to regulate this issue is mandated by WHO, FAO, OIE and UNEP. In particular, antibiotic resistance issues are considered within the framework of the Codex Alimentarius Commission, established by FAO together with WHO.

The implementation of measures to protect health is one of the nine main areas of social protection and involves ensuring the required level of health of the population through access to necessary health technologies, in particular — to basic medical services, as well as medicines and medical devices. In accordance with the Constitution of the organization, the ILO, along with WHO, plays an important role in the formation of international legal mechanisms that ensure access to health technologies. In particular, mention should be made of the Social Security (Minimum Standards) Convention, 1952, the Medical Care and Sickness Benefit Convention No. 130, 1969 and the Recommendation No. 202 on Social Protection Minimum Levels, 2012.

The WTO agreements are essential in regulating access to health technologies. The adoption of the TRIPS Agreement, which was aimed at simplifying access to technologies for the development of technological progress, as well as maintaining a balance of interests of producers and consumers, had a significant impact on the formation of a modern system for regulating access to healthcare technologies. The increase in the participation of the private sector in organizing the provision of medical and social assistance had a significant impact on the increase in the rate of trade in medical services. The GATS is the first and only universal agreement to regulate trade in services, including provisions for technology transfer for the benefit of developing countries.

4. The role of health technologies in achieving national priorities

Over the past decades, issues of access to health technologies have gradually been integrated into the national priorities of each state as an important component of socio-economic well-being, the health of military personnel, as well as protection against non-military threats, serving as the basis for rethinking national security strategies. Every 5 years, starting from 2009, the President of the Russian Federation approves the National Security Strategy of the Russian Federation. Each of the three versions of the document addressed the issue of regulation of the transfer of health technologies to some extent.[7]

In particular, one of the priority tasks was determined to overcome technological dependence through the development of the domestic pharmaceutical industry to ensure guaranteed access of the population to medicines. In the latest version of the strategy, scientific and technological development is identified as one of the main priorities of national security, including the tasks of developing promising high technologies in the field of medicine and creating reserves of medical applications to counter various threats.[8]

The pandemic of coronavirus infection served as an incentive for the further development of the safety concept through the approval of the Federal Law "On the Biological Security of the Russian Federation" at the end of 2020, which formulated the tasks for the development, production and implementation of new technologies related to the use of pathogens, as well as the organization of scientific activities in the field of biological safety.

In the United States, health issues that have a direct impact on the security of the country have long been considered within the framework of separate strategies. Since 2009, the National Health Security Strategies (NHSS) have been developed by the Department of Health and Human Services to ensure timely responses to health emergencies. As amended by the strategy for 2015–2018 a separate goal is formulated to strengthen national capacities in the development, production and effective use of various medicinal products, including medicines. In the latest version of the

[7] Decree of the President of the Russian Federation of 12.05. 2009 №537 "Strategy of national security of the Russian Federation until 2020". National Security Strategy of the Russian Federation, approved by Presidential Decree of 31.12.2015 No. 683 // SPS Consultant Plus.

[8] Presidential Decree of 02.07.2021 No. 400 "On the National Security Strategy of the Russian Federation"// SPS Consultant Plus.

Strategy 2019–2022 various aspects of access to health technologies are addressed [National Health Security Straegy 2019–2022: 2021]. In particular, the document emphasizes the need to ensure cybersecurity in the context of the spread of digital technologies in the medical care system, and also draws attention to the need to develop gene-cell technologies as the basis for the provision of personalized care. The document also pays special attention to the potential threat of the deliberate use of biological and chemical substances in the course of hostilities or terrorist activity.

Health issues figure in the Safety Strategies of regional organizations. Guided by Article 152 of the Treaty establishing the European Community, the activities of the state should complement the national policy aimed at improving public health, preventing the spread of diseases. In November 2009, the European Commission developed a working document on health security in the EU and internationally, summarizing the EU's priorities in addressing various threats, including ensuring the development of necessary health technologies. In July 2020. The European Commission has adopted the EU Security Strategy for the period 2020–2025.[9] The document emphasizes the dependence of modern society on various technologies, which was vividly demonstrated in the context of the COVID-19 pandemic, and formulates the task of building capacity to quickly and timely confront health emergencies. The document also draws attention to the negative impact of the development of technology shortages on the development of criminal activity and significant consequences for the medical care system.

Thus, based on the analysis of the national security strategies of the leading world powers, a conclusion should be drawn about the final formation of the health sector as one of the most important components of state security and the determination of national goals to create the necessary conditions for access to health technologies.

5. Human rights and access to health technologies

Access to health technologies is one of the most important components of realizing the right to the highest attainable standard of health, as articulated in all universal and regional human rights instruments. In particular, in Art. 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) defines the main components of the hu-

[9] Communication from the Commission to the European Parliament, The European Council, The Council, The European Economic and Social Committee and the Committee of the Regions on the EU Security Union Strategy COM/2020/605 final

man right to health, including the need to ensure adequate health care, which implies access to health technologies. Access to health technology as a fundamental element of the human right to health was subsequently highlighted in General Comment 14, which enshrined four interrelated elements of this concept: availability, accessibility, acceptability, quality (AAAQs).[10] The right to access to health technologies was included in the Declaration on the Right to Development, adopted by the UN General Assembly in 1986, which formulated the right of every person to participate in such economic, social, cultural and political development, in which it is possible to fully realize all human rights and freedoms, and established that states must ensure equality of opportunity in terms of access to basic resources in the field of health protection [Khabriev R.U., Abashidze A.Kh., Malichenko V.S., 2016: 16–22].

Judicial decisions must be consulted to address the practical aspects of the relationship between the right to health and access to health technologies. At the regional level, the decisions of the human rights courts have not directly addressed access to health technology as a component of the right to health, with the exception of a number of decisions of the Inter-American Court of Human Rights.[11] However, at the national level, there is more extensive jurisprudence recognizing the importance of access to health technologies in realizing the human right to health. This trend is largely due to an increase in the frequency of citizens' appeals to international courts due to limited access to healthcare technologies, especially in the developing regions of the world. In India, back in 1987 by a Supreme Court decision, health protection, including programs to ensure access to medicines at reasonable prices in accordance with the WHO List, was defined as part of the right to life as enshrined in the country's constitution.[12] Subsequently, the Karnataka High Court formulated in its decision that restricting access to medicines under the WHO List is a violation of state policy in the field of drug provision.[13] Subsequently, a series of decisions

[10] Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14 on the right to the highest attainable standard of health, 11 August 2000, UN Doc. E/C.12/2000/4, para 17. Available at: http://www1.umn.edu/humanrts/gencomm/escgencom14.htm (accessed: 20.04.2019)

[11] IACtHR, Caso Duque Vs Colombia. Excepciones Preliminares, Fondo, Reparaciones y Costas. Ruling of 26 February, 2016, Serie C, No 310, para. 174; Caso Cuscul Pivaral y otros vs Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas, Ruling of 23 August, 2018, Serie C, No 359, para 108–114.

[12] Vincent Panikurlangara v Union of India, 1987 AIR 990, Judgement of 03 March 1987.

[13] KS Gopinath v Union of India, Karnataka High Court, 21618/2002, Judgement of 12 November 2002, para 19.

of the Supreme Court of India formulated the need to increase the availability of antiretroviral drugs for the treatment of HIV / AIDS.[14] The Constitutional Court of South Africa, guided by the right to health, enshrined in the country's Constitution, found that the restrictions imposed by the government on access to antiretroviral drugs were unreasonable.[15] In Nigeria, the Federal High Court, based on Art. 16 of the African Charter on Human and Peoples' Rights, which enshrines the human right to health, defined as violations of limiting the access of prisoners with HIV / AIDS to necessary medical care.[16] The Constitutional Chamber of the Supreme Court of Costa Rica issued two judgments in 1997 making antiretroviral treatment mandatory for the social security system.[17] Similarly, in deciding on access to health care, the Mexican Supreme Court included the provision of antiretroviral drugs on the national equivalent of the WHO List as an integral part of the constitutional right to health.

The right to access to health technologies, as well as the right to development, are inextricably linked with the right to access the achievements of scientific progress, as well as the right to participate in scientific progress, formulated in Art. 27 of the Universal Declaration of Human Rights (UDHR); Art. 15 para 1 (b) ICEXP, as well as in regional treaties, in particular in: Art. 13 para 2 of the American Declaration of the Rights and Duties of Man of 1948; Art. 14 par 1 c) of the Additional Protocol to the 1988 American Convention on Human Rights in the Field of Economic, Social and Cultural Rights ("San Salvador Protocol"); Art. 1 of Protocol No. 1 to the 1952 Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter — the European Convention on Human Rights). In practice, the implementation of the right to access the achievements of scientific progress involves finding a balance with the need to ensure the protection of intellectual property rights. According to the position of the CESCR, intellectual property is a social product with a corresponding function, which obliges states to form legal regimes of exclusive rights of developers to ensure a balance of compliance with the rights enshrined in the ICESCR.

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[14] Sahara House v Union of India and others, Writ Petitions 535 of 1998, 512 of 1999, 61 of 2003 and 311 of 2003. Order of 2 December 2013.

[15] Minister of Health et al. v. Treatment Action Campaign et al, Constitutional Court of South Africa, Case CCT 8/02, Judgement of July, 2002, para 34-36 and Order of the Court.

[16] Festus Odefe and Others v Attorney-General and Others, Federal High Court of Nigeria, Port Hartcourt judicial division, Suit FHC/PH/CS/680/2003, Decision of 23 February 2004.

[17] Luis Guillermo Murillo Rodríguez et al v Caja Costarricense de Seguro Social, Sala Constitucional, Decisión 6096-97, 1997; William García Álvarez v Caja Costarricense de Seguro Social, Decisión 5934-97, 1997.

6. Development of legal regulation of access to health technologies

As noted earlier, the circulation of health technologies is a complex process, each stage of which is governed by acts of a universal and regional nature that shape various branches of international law, expanding or restricting access to health technologies.

Ensuring the affordability of healthcare technologies is primarily associated with international and national regulations governing the protection of the exclusive rights of healthcare technology developers. The institution of patent protection has undoubtedly become the main systematic development of innovative activity, which is especially noticeable in the segment of healthcare technologies, but at the same time, under certain circumstances, it can be a significant barrier limiting the realization of the human right to health.

However, patent protection, being the most discussed problem in scientific publications in recent years, is only the tip of the iceberg. Health emergencies have highlighted the problem of lack of necessary technology at the time of the spread of disease. Timely development of health technologies is possible through the creation of the necessary mechanisms for the transfer of scientific data and biological materials, as well as adequate investment in research activities. Another barrier to access to health technologies is the lack of essential medical supplies. Countering the shortage is possible by creating special planning programs and organizing the procurement of vital drugs and medical devices, both at the international and regional levels. An important way to counter the deficit is to create the necessary production capacity to meet the needs of a particular region.

7. Legal mechanisms for the transfer of health technologies

Technology transfer regulation has a special place in international law, given that 48 of the 169 targets identified under the SDG are directly related to access to technology. In particular, ensuring access to technology is highlighted as a separate area under SDG 17 to expand tripartite, regional and international cooperation in the fields of science, technology and innovation between existing mechanisms at the UN level, as well as through the global mechanism for promoting technology transfer.[18]

[18] UN General Assembly Resolution A / RES / 70/1. 2015. Transforming Our World: The 2030 Agenda for Sustainable Development.

Today, there are practically no acts of a universal nature that contribute to the systematic transfer of health technologies. The only international legal mechanisms that allow the transfer of health technology directly are compulsory and voluntary licensing, which are separately considered later in the article. Some success can be seen in the development of mechanisms to facilitate the transfer of scientific data required for research and development of health technologies. In particular, the timely exchange of pathogens and the sharing of research results are essential in the development of various health technologies to respond to infectious pandemics. In particular, the 1992 Convention on Biological Diversity emphasizes the importance of access to genetic resources and technologies in meeting health needs. It is important to note that the provisions of the Convention apply to viruses containing nucleic acids in their structure, which should be classified as genetic material. Access to selected viruses is essential in developing scientific capacity and the timely development of health technologies needed to respond to infectious pandemics.

Another international communication mechanism for health technology development is the Pandemic Influenza Preparedness Framework, which recognizes the principle of sovereign rights of states over their biological resources and defines the main goal of sharing influenza viruses with pandemic potential, as well as scientific data and developments. A unique aspect of the Facility is the involvement of the private sector, through two types of "standard material transfer agreements" that ensure the transfer of virus samples to developers, as well as the reciprocal obligations of the manufacturer in the form of specific amounts of vaccines and other benefits provided. Within the framework of the mechanism, three categories of parties to the agreement are distinguished: manufacturers of vaccines and antiviral drugs (category A), manufacturers of medical devices (category B), research institute (category B). Today, 73 agreements with research institutes are in force, within the framework of which it is envisaged to conduct educational events for the creation of state research centers, and to license the production of developed technologies. 14 existing agreements with pharmaceutical manufacturers ensured that 420 million doses of vaccines would be provided to countries in need in the event of a pandemic, as well as 10 million courses of antiviral drugs. In addition, under two agreements with manufacturers of medical devices, 250 thousand diagnostic kits and 25 million disposable syringes have been reserved.[19]

[19] Pandemic Influenza Preparedness Framework: annual progress report, 1 January — 31 December 2020. Geneva, 2021.

At the national level, a more systemic, albeit not unified, approach has emerged to the creation of regulatory mechanisms that create favorable conditions for the production of necessary health technologies and the formation of scientific potential in this area. The turning point in the development of the health technology transfer system in the United States was the adoption of the Stevenson-Wydler Act of 1980[20], which established a mechanism for the transfer of technology from government agencies to the private sector under the Bayh-Dole Act of 1980, which allowed universities, small businesses, and non-profit organizations to patent and license technologies directly developed through federal research or cooperation agreements.[21]

In the Russian Federation the formation of regulatory mechanisms to facilitate the development of the transfer of healthcare technologies began relatively recently and was largely aimed at providing financial support and other economic preferences for domestic enterprises in the medical and pharmaceutical industries, as well as foreign companies planning to transfer technology to Russia. The main document for the development of national potential in the development and production of health technologies was the "State Program for the Development of the Medical and Pharmaceutical Industry 2013-2020", which defined targeted measures to ensure the development and production of medicines and medical devices in the country. Another mechanism for the development of the transfer of technologies for their production on the territory of the Russian Federation was the Special Investment Agreement (SPIK) provided for by the Federal Law of December 31, 2014 No. 488-FZ (as amended on December 31, 2017) "On industrial policy in the Russian Federation". The SPIK is concluded for technologies from 15 industries, including the medical and pharmaceutical sector, included in the list of modern technologies, formed on the basis of the rules approved by the Decree of the Government of the Russian Federation No. 319 of March 21, 2020. The SPIK is concluded for a period not exceeding 10 years, and provides for a number of preferences from the state in case of production on the territory of the Russian Federation.

8. Legal regulation of researches

Research is the backbone of access to health technology. Adequate legal regulation of research activities, together with the necessary volumes of in-

[20] Stevenson-Wydler Act of 1980. Public Law, 96–480.

[21] The Bayh-Dole Act of 1980. Public Law, 96, 517.

vestments, make it possible to create favorable conditions for the development of the necessary health technologies. One of the main conditions for the allocation of financing from companies is the attractiveness of the research area in the context of the return on investment. Traditionally, fundamental research is funded by the state, while applied research aimed at developing a specific technology (drug, medical device, etc.) is supported by private companies [Schweitzer S.O., Lu Z.J., 2018: 39]. At the same time, the lack of sufficient government funding is compensated by the provision of various kinds of preferences to manufacturers.

The cost of research and development is constantly increasing. It cost about $1.3 billion to market a drug in 2010, up from 138 million in 1975 [DiMasi J.A., Grabowski H.G., 2007: 469–479]; [DiMasi J.A.,, Grabowski H.G., 2003: 151–185].[22] Thus, over the past 35 years, research spending has increased by almost 10 times. The ratio of R&D investment to pharmaceutical sales is five times that of the average US manufacturing company. [23] The growth rate of the pharmaceutical market has undoubtedly contributed to the increase in research and development expenditures. To date, the number of clinical trials of drugs has reached an all-time high. More than 850 clinical trials are underway for COVID-19 vaccines and drugs alone. Total spending on drug research in 2020 was $198 billion.[24] At the same time, the volume of investments of the 11 largest pharmaceutical manufacturers reaches $86.3 billion.[25]

The high cost of medicines and other health technologies is in most cases justified by high investment in research activities. At the same time, often the bulk of funding falls on the early stages of research, which are carried out at the expense of state budgets in research organizations and subsequently transferred under certain conditions to private companies. As noted in the report of the Lancet Commission on Access to Essential Medicines for Universal Health Coverage, there is a need for national procedures that take into account public investment in health technology pricing [Wirtz V.J., Hogerzeil H.V., Gray A.L., 2017: 403–476].

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[22] Available at: https://www.ghtcoalition.org/pdf/Saving-lives-and-creating-impact-summary.pdf (accessed: 19.09.2021)

[23] USCBO. Research and Development in the Pharmaceutical Industry. Congress of the United States, Congressional Budget Office. 2006. P. 65. Available at: https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/10-02-drugr-d.pdf (accessed: 29.08.2021)

[24] Available at: https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/ (accessed: 29.08.2021)

[25] Available at: https://www.evaluate.com/vantage/articles/data-insights/other-data/roche-remains-big-pharmas-biggest-rd-spender (accessed: 29.08.2021)

Investment in the development of certain health technologies is grossly disproportionate. For example, the number of clinical studies in the field of oncology significantly exceeds the number of studies on the treatment of infectious diseases, which are common only in a limited number of countries in the world. The mechanisms of patent protection and data exclusivity established in industrialized countries in general, as well as other preferences, facilitate drug development without significant additional therapeutic benefits in areas with a large number of different treatment options or *me too drugs*, thereby limiting access to the necessary drugs in developed countries due to the high cost, as well as the lack of developed technologies for the treatment of diseases in developing countries.

9. The role of intellectual property rights protection mechanisms

Among the main factors influencing access to health technologies, special attention in international organizations and scientific research is paid to mechanisms for protecting the exclusive rights of developers to the results of intellectual activity. Registration of a patent provides for the full disclosure of the data of their inventions, allowing other subjects to use this technology in the future. In this case, the applicant receives exclusive rights to the invention, valid for a certain period of time [Abashidze A.Kh., Malichenko V.S., 2019: 62–79].

To date, patent protection is undoubtedly the basic legal instrument that allows its owners to single-handedly set the price of technology to ensure reimbursement of research and development costs. It is not possible to predict the required volume of investments in development at the initial stages due to the fact that in practice only a few initially selected molecules of drugs or prototypes of medical devices demonstrate the indicators required for registration.

Almost until the end of the 20th century, approaches to ensuring patent protection for healthcare technologies differed significantly from state to state. By the beginning of the Uruguay Round of trade negotiations in 1986, 49 out of 98 states parties to the Paris Convention of 1883 excluded pharmaceutical products from the list of objects subject to patent protection, 10 — pharmaceutical technological processes, and 22 — chemical technological processes [Dutfield G., 2003: 304]. Countries differed in terms of the duration of patent protection and / or the presence of other restrictions on the rights of patent holders. Such exceptions were wide-

spread in Western countries as well. For example, pharmaceutical patents were not granted in the following European countries: France (until 1960), Switzerland (until 1977), Italy (until 1978), Sweden (until 1978), and Spain (until 1992).

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was the first multilateral treaty to enshrine the main criteria for patentability and approve uniform standards for granting patents for various products, including health technologies. The Agreement also states that the term of the protection granted is 20 years from the date of filing of the application. The TRIPS Agreement provided for a number of transition periods, including the introduction of patenting, to ensure the phased implementation of commitments.

It is generally agreed that in most studies patent protection is a major factor in driving high prices for medicines and other medical uses. At the same time, the price level can differ significantly depending on the region of the world, which is increasingly being discussed by the governments of various countries, as well as international organizations. In particular, the sharp rise in the price of patented drugs in the United States was the subject of an investigation by the House of Representatives Oversight and Reform Committee in 2020.[26]

The coronavirus pandemic has exacerbated the long-debated possibility of voluntarily waiving patent protection for selected health technologies in emergencies. So, in October 2020, India and South Africa proposed to the WTO to abandon patent protection for vaccines in the context of a pandemic to ensure their international availability.[27] This proposal was supported by 100 countries from two key WTO groups: the African group and the group of least developed countries, but was rejected by the EU, the United States and a number of industrialized countries.

In the context of the discussion of the role of patent protection, the criteria of patentability are an important issue, especially in the case of

[26] The US House Committee on Oversight and Reform. Investigation of Skyrocketing Prescription Drug Prices. Available at: https://oversight.house.gov/investigations/investigation-of-skyrocketing-prescription-drug-prices (accessed: 29.08.2021)

The US House Committee on Oversight and Reform. Oversight Committee Announces Major Hearings with Drug Company CEOs after 18-Month Investigation. Available at: https://oversight.house.gov/news/pressreleases/oversight-committee-announces-major-hear (accessed: 29.08.2021)

[27] World Trade Organization. Waiver from certain provisions of the TRIPS agreement for the prevention, containment, and treatment of COVID-19: communication from India and South Africa IP/C/W/669, 2020. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (accessed: 29.08.2021)

the use of artificial intelligence technologies in the development of health technologies. In 1988, the UK became the first country to enact the Copyright, Industrial Designs and Patents Act 1998 (CDPA), which contains provisions for artificial intelligence works. Since 1973, the US Copyright Office has enforced a human authorship requirement that prohibits registration of "works created by a machine or a simple mechanical process that works randomly or automatically without any creative input or intervention from a human author."

None of the jurisdictions have laws or regulations regarding artificial intelligence inventions. The growing role of artificial intelligence in the development of various technologies is causing significant debate among academia and industry, especially with regard to the development of health technologies.[28] In such conditions, there is a high probability of revising the criterion of patentability, as well as signs of violation of the exclusive rights of technology developers.

Along with patent protection, an increasing impact on the availability of healthcare technologies is exerted by mechanisms for protecting data from clinical trials, limiting the possibility of their use by other manufacturers to register similar technologies for a period specified by law. In the United States, data exclusivity regulation was introduced under the Drug Price Competition and Patent Extension Act of 1984, also known as the Hatch-Waxman Act, which provided 5 years of protection for low molecular weight chemicals, 3 years of protection for registrations of new indications of registered drugs. drugs, 4 years for biological drugs.

At almost the same time, Directive 87/21 / EEC of 1987 was adopted in the EU, which established a 6-year period for protecting the exclusivity of data used in newly registered medicinal products. In addition, EU member states were empowered to extend the data exclusivity protection period up to 10 years if there is a substantial need from the healthcare system. In 2004, as a result of the harmonization of regulation throughout the EU, a unified data exclusivity protection regime was formed, which implies the provision of 8 years of protection for all drugs, an additional two years within which it is possible to register generic drugs without putting them into civil circulation, as well as an additional year upon registration a new indication for use.[29]

[28] Intelligent drug discovery Powered by AI, Deloitte, 2019. Available at: https://www2.deloitte.com/us/en/insights/industry/life-sciences/artificial-intelligence-biopharma-intelligent-drug-discovery.html (accessed: 02.09.2021)

[29] Directive 2004/27/EC on the Community code relating to medicinal products for human use. OJ L136/34.

It is important to note that abandoning patent protection will not allow sustainable access to health technologies, but rather reduce the pace of research and development. It is necessary to take into account the existing global inequality in production capacity. If a certain country seeking compulsory licensing does not find a manufacturer with the ability and willingness to carry out the required production, the issue of authorization remains controversial. The economic problems of the least developed countries, where the presence of local pharmaceutical manufacturers is limited, may impede wider access to essential medicines in emergencies, despite the increased flexibility of the TRIPS Agreement.

10. Application of the "flexible mechanisms" of the TRIPS Agreement

The restriction of access to healthcare technologies due to their high cost determined the advisability of using special mechanisms to ensure the lawful production of more affordable analogues. The TRIPS Agreement contains a number of provisions that can be used by member countries in certain circumstances to overcome patent protection and, in particular, to expand access to medicines. These provisions, commonly referred to as the "flexible provisions of the TRIPS Agreement in the field of public health", provide for a number of important mechanisms and guarantees that countries can use to reduce prices and expand access to patented and non-patented health technologies.

One of these mechanisms is compulsory licensing, which has been used as a tool to ensure access to innovation in various regions of the world for more than a century. The introduction of compulsory licensing was discussed in the British Monopoly Act of 1623, the first US patent law of 1790, and the patent regulation of Saxony (Germany) in 1853 [Chien C., 2003: 853-907]. Compulsory licensing was actively used in Canada from 1923 until joining the North American Free Trade Agreement (NAFTA). In the period from 1979 to 1985, United States and other developed economies around the world have repeatedly attempted to initiate a revision of the Paris Convention to limit the possibility of compulsory licensing.

The US Trade Mission defines compulsory licensing "as a permit granted under special conditions to third parties to use patented products without the permission of the patent owner". A compulsory license may be issued to one or more persons to use a patented product without the permission of the patentee, provided that sufficient monetary compensation is paid to the patentee.

TRIPS Agreement Art. 31 does not provide for any restrictions on the grounds on which compulsory licenses can be issued, provided that the procedure for their issuance meets the established minimum requirements. At the same time, at the national level, additional requirements may be provided for the application of compulsory licensing. For example, in Ireland, compulsory licenses for any reason can only be granted 3 years after the grant of the patent. This is usually not a significant practical limitation on the use of compulsory licenses, given that it takes much longer to obtain regulatory approval for the use of the technology.

The COVID-19 pandemic has provided a systemic rethinking of the use of compulsory licensing in various regions of the world. For example, in 2020, Canada passed laws to facilitate the accelerated issuance of compulsory licenses. Germany has passed the Infectious Disease Prevention and Control Act, empowering the Ministry of Health to grant compulsory licenses under section 13 of the Patent Act in the event of a national epidemic being declared. Similar measures were also taken in France by the Emergency Law No. 2020-290 of March 23, 2020 to combat the COVID-19 epidemic, which introduced a new article L.3131-15 in the Public Health Code authorizing the Prime Minister to act in order to ensure public health, including the provision of public use of patented inventions.

In the Russian Federation, the use of compulsory licensing in the interests of defense and security with the payment of commensurate compensation to the patent holder is permitted by Art. 1360 of the Civil Code of the Russian Federation. It should be noted, however, that until April 2021, the article did not provide for any special provisions for medicinal products. For the first time, guided by the provisions of the aforementioned article, in December 2020, by the order of the Government of the Russian Federation, the domestic manufacturer was granted the right to manufacture a drug for the treatment of COVID-19. Federal Law No. 107-FZ of April 30, 2021 amended Art. 1360, which supplemented the grounds for granting a compulsory license with the purpose of ensuring the protection of the life and health of citizens.

When discussing the issue of compulsory licensing, it is necessary to mention the possibility of the patent owner voluntarily granting the right to use the patent to third parties on the basis of licensing agreements that allow a third party to use intellectual property with payment of royalties (licensing fees), in relation to a certain area of use, in a certain territory and for a certain period, which may coincide with the term of the patent. The development of the trend towards the transfer of rights to manufacture drugs, in particular for the treatment of HIV / AIDS, under license agree-

ments to manufacturers of generic drugs has stimulated the creation of a patent pool of drugs [Bermudez H., 2010: 37].

As part of the negotiation process, the patent pool reaches an agreement with patent holders on the possibility of granting the corresponding rights for the production of medicines for the treatment of HIV, hepatitis and tuberculosis to other manufacturers on a non-exclusive and non-discriminatory basis for distribution in countries with a low level of economic development. At the same time, patent holders receive a license fee for the granted access to intellectual property.

11. Global partnerships for the procurement of health technologies

Differing levels of development of health systems, as well as disproportionate levels of well-being in different regions of the world, create barriers to access to life-saving health technologies. This determined the need for interaction between international organizations, non-governmental bodies, transnational corporations, etc., in relation to providing access to some of the most popular healthcare technologies. As an example, first of all, it is necessary to mention various global initiatives for the procurement of funds for the prevention and treatment of HIV / AIDS, tuberculosis and malaria in the developing regions of the world, such as UNITAID, Gates Foundation, Global Alliance for Vaccines and Immunization, The Global Fund to Fight AIDS, Tuberculosis and Malaria. The COVID-19 pandemic has heightened the need to organize global initiatives to ensure access to health technologies. The rapid development of the deficit of various health technologies has determined the need for the formation of global initiatives to support the most affected countries in the world. In 2020, WHO launched the Accelerating Access to COVID-19 (ACT) Initiative in four pillars: access to diagnostics, treatment, vaccines and health systems strengthening. In particular, the goal of expanding access to vaccines, led by WHO and the GAVI Alliance, envisages the creation of the necessary production capacity and an equitable distribution of 2 billion doses of vaccines by the end of 2021.

An analysis of the specifics of access to health technologies demonstrated the leading positions of various global initiatives that are not traditional subjects of international law, but have comparable political influence with WHO. The increasing role of global partnerships in international relations rightly raises the question of revising the concept of legal personality in international law, as well as determining the possibility of bringing these

partnerships to legal responsibility in the event of harm to the health and well-being of the population of individual states.

Bilateral pre-purchase agreements between manufacturers and the EU have had a significant impact on the availability of vaccines. The idea of creating a single mechanism for the procurement of healthcare technologies began to be discussed at the EU platform since the outbreak of the SARS virus and avian influenza. Decision No. 1082/2013 / EU "On Serious Cross-Border Threats to Health" formed the legal basis for the adoption in April 2014 by the European Commission of the Joint Procurement Agreement for the supply of various medical products in order to counter cross-border threats to health.

The developed Vaccine Strategy, adopted by the European Commission in June 2020, emphasizes the need for a centralized procurement process for vaccines. As part of supporting the development and manufacture of vaccines, the Commission enters into agreements with individual manufacturers on behalf of Member States. In exchange for the right to buy a certain number of doses of vaccine at a given time and price, a portion of the initial cost to the vaccine manufacturer will be funded from the Emergency Support Instrument (ESI). In parallel, EU legislation provides for other mechanisms to ensure a systematic response to threats and challenges in the field of health protection. Within the framework of the special "rescEU" procedure provided for by the EU civil protection mechanism, the European Commission's Directorate General for Civil Protection and Humanitarian Aid is forming a special reserve of vital medical products to counter the development of shortages due to the coronavirus pandemic.

The EU experience is indicative in the context of the formation of a single pharmaceutical market and the market for medical devices of the EAEU countries and the prospects for the formation of mechanisms for the centralized procurement of certain healthcare technologies in certain situations that pose a threat to the security of states.

12. The importance of harmonization processes in ensuring safety and quality of healthcare technologies

Today, due to the processes of globalization, the main stages of the circulation of healthcare technologies, including the development, production, transportation, circulation, are no longer carried out within one state, suggesting the involvement of different regions of the world in each stage. However, differences in the level of socio-economic well-being of states

have a significant impact, both on the organizational and technical potential of the necessary control and supervisory functions, and on the level of development of the system of legal regulation of the circulation of health technologies.

Harmonization of regulation of the healthcare technologies circulation, implemented at the regional level, is primarily aimed at introducing a unified regulatory framework that allows ensuring the required standard of safety and quality. Most of the initiatives to harmonize regulation of the circulation of health technologies are implemented on the basis of regional economic integration processes, among which the European Union, the Eurasian Economic Union, and the African Union should be mentioned.

The regulation of the circulation of medicinal products in the EU is carried out on the basis of Directives and Regulations. The regulation primarily acts as a tool for the unification of law. The EU is a vivid example of not only harmonization of regulation in the field of health protection and, in particular, the circulation of health technologies throughout the space of the member states, but also the formation of supranational structures responsible for the coordination and implementation of these processes. Such a structure is the European Medicines Agency (EMA), established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of March 31, 2004.

The example of the European Union clearly demonstrates the effectiveness of the supranational system of regulation of the most important stages of the health technologies circulation, and this approach allows to ensure control over the safety and availability of these technologies. The EAEU acts primarily as an international organization for regional economic integration, affecting such areas of regulation as economics, science, education, culture, ecology and trade. On January 1, 2021, the provisions governing the activities of the single pharmaceutical market of the EAEU countries came into force, in many respects repeating the principle of convergence of regulation of healthcare technologies that has emerged within the EU. Undoubtedly, the creation of single markets is primarily aimed at the maximum convergence of the regulation of the medical and pharmaceutical industries of the EAEU member states with the European Union.

Harmonization processes gradually began to develop in the African region as well. In January 2005, the New Partnership for Africa's Development (NEPAD) outlined an Africa Pharmaceutical Development Plan to expand access to safe, quality and effective health technologies. Subsequently, in 2009, NEPAD also launched the African Medicines Regulatory Harmonization (AMRH) Initiative. On the basis of the initiative, a draft

African Union Model Law on the Regulation of Medical Products was developed in January 2016 and subsequently approved by the Health, Labor and Social Affairs Committee of the African Union's Pan-African Parliament. The document was aimed at harmonizing the regulation of various health technologies. The African Union Assembly, at its 32nd Ordinary Session in Addis Ababa in 2019, adopted an agreement establishing the African Medicines Agency (AMA), which will expand to 55 countries in the African region, forming 8 different regional economic associations. The treaty will enter into force upon ratification by 15 countries of the African region. The current multi-country vaccine testing model, the African Vaccine Regulatory Forum (AVAREF), is expected to be expanded through the work of the African Agency.

Conclusion

The increase in the frequency of emergencies in the field of health has shown that, despite the significant technological progress achieved, which makes it possible to provide treatment for deadly diseases, as well as rethinking the importance of health technologies in achieving international development goals, ensuring national security and the socio-economic well-being of states, there is currently no systematic approach to regulating the transfer of health technologies at the global level. Of paramount importance for ensuring timely access to healthcare technologies is the formation of a legal mechanism that ensures an increase in the pace of development of technologies necessary to counter life-threatening diseases. Among such measures, it is necessary to mention the provision of sustainable funding, the transfer of research data between states, as well as access to biological materials necessary for development. The positive experience in the formation of patent pools determines the need for the systematic use of voluntary licensing of healthcare technologies for the production of medical products in the required volumes, as well as the development of local production facilities in the developing regions of the world. In the context of the formation of a single market for pharmaceuticals and medical devices in the EAEU countries, the experience of the European and African regions with regard to the creation of a supranational regulatory body regulating the circulation of health technologies is useful. The creation within the EAEU of a similar organization with supranational powers to regulate the circulation of health technologies will help to ensure control of safety, quality and efficiency. Solving the set tasks will require the systematic involvement of international organizations and the application of various branches of inter-

national law to form acts of a universal nature aimed at ensuring sustainable access to the necessary healthcare technologies.

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COVID-19: Legal Regulation of Universal Vaccination

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Abstract

The topic of this article is relevant, first of all, due to the fact that at the moment it is objectively impossible to deny the acquisition of the COVID-19 pandemic and its consequences as a kind of main indicator of socio-economic processes and a mechanism for legitimizing the state system of regulation and management in covid and post-covid conditions. The subject of the article is the legal regulation of mandatory vaccination against COVID-19. The purpose of the study is to identify the problems of legal regulation of the process of mandatory vaccination against COVID-19 through the prism of the human right to health protection and medical care in the system of universal values. This research is based on a combination of groups of general scientific methods (induction, deduction, analysis, synthesis) and special methods of legal science (formal legal, comparative legal and others). The authors carried out a conceptual analysis of the human right to health protection and medical care in the context of domestic law, as well as administrative and legal aspects of mandatory vaccination against COVID-19 based on the analysis of the generalized experience of two macro-regions of Moscow and the Moscow region. According to the results of the study, the authors come to the following key conclusions: firstly, the chief state sanitary doctor of the subject of the Russian Federation has an objective right dictated by the norms of domestic legislation to issue an executive-executive-administrative act on the mandatory vaccination in a pandemic; secondly, the employer is obliged to suspend from work (not to hire) citizens who refused vaccination only if it is a question of works named in the List of works, the performance of which is associated with a high risk of infectious diseases. Such measures cannot be applied to employees performing other types of work; thirdly, failure by an organization/individual entrepreneur to comply with the

resolution of the chief state sanitary doctor entails appropriate measures of legal responsibility provided for by the norms of the current legislation of the Russian Federation.

Keywords

the human right to health protection and medical care, COVID-19, pandemic, restrictions, anti-medical measures, Chief sanitary doctor, mandatory vaccination, administrative and legal regulation.

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Introduction

The COVID-19 pandemic, which started in 2020, has informed the processes that have exercised a mostly destructive influence on the majority of systemically important clusters of the socio-economic space of the Russian Federation. Several months from now, it is going to be 2 years since the first case of the new infectious disease was first recorded in the RF. According to an expert estimate of Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor) chief officer Anna Popova, "The first case of COVID-19 in Russia was recorded on March 1, 2020. The two cases of the illness brought from the People's Republic of China in February 2020 are not taken into account."[1]

So, soon it is going to be two years since the nation was first exposed to the new infection it is struggling to contain — this period is long enough to provide a sufficient number of observations for analyzing the dynamically changing situation and revisiting the current models of behavior and the relevant legislation. In particular, it is now obvious that because healthcare facilities are used to full capacity due to the COVID-19 pandemic, society and the state are faced with the challenges of modernizing the constitutional foundation of the right to health protection and medical assistance / medical care. These writers consider that in view of the special status this right is accorded in the RF's Constitution, the state and society should focus their efforts on bringing this right in line with modern realities.

[1] Available at: https://www.interfax.ru/russia/709883 (accessed: Aug.10, 2021)

The COVID-19 response measures in Russia are quite varied, although vaccination has been prioritized, according to experts [Surovenko T.N., 2021: 70–77]; [Kharchenko E.P., 2021: 4–19]. In view of the above, the vaccination campaign's most contentious aspects are administrative and legal, related to legitimation of the vaccination in the Russia's legal space. In particular, it was for the first time that Moscow mayor and the governor of Moskovskaya Oblast' (Moscow Area) introduced mandatory vaccination for certain groups of people pursuant to orders issued by chief public health officers[2]. The mentioned bylaws became a sort of catalyst for the start of the universal COVID-19 vaccination campaign across the country.

Certain issues of vaccination, including the COVID-19 vaccination, have been explored by scholars from different disciplines. Thus, legal aspects of this problem have been addressed by social scientists from Samoa [Ramona B., 2020: 116–125]; the USA [Caitlain L., 2020], the UK [Kevin H., Erin W., 2020]. In particular, the researchers explore how governments reconsider their strategies and change their vaccination policies. These writers agree with the mentioned researchers in that today there are two main approaches: informing people and giving them the freedom of choice (Russia, Germany, Austria) and mandatory vaccination (Saudi Arabia, Indonesia, Israel).

Looking from the perspective of the COVID-19 pandemic, some legal scholars [Hans-Uwe S., Alexander K., Martin B., 2020: 1-5]; [Maltezou C., Androula P., Athanasios T., 2021: 1–12] insist on the need for revising the international legal standards, norms and principles adopted and recommended by the World Health Organization (WHO) since they do not provide an unequivocal answer regarding mandatory vaccination and violate human rights. These writers consider this stance to be totally justified and subscribes to it because the existing international legal standards, norms and principles adopted and recommended by the WHO need to be brought up to date fast in order to become, at a supranational legal level, a guarantee of the entire array of anti-COVID measures carried out at national levels.

It would seem logical to suppose that the present realities of the COVID-19 pandemic and its consequences are poised to become, for a long time to come, the main focus of integrated research combining disciplines from different fields of social sciences and the humanities because

[2] See: Order No. 1 of chief public health officer of Moscow. June 15, 2021. "On Prophylactic Vaccination of Certain Vulnerable Population Groups." Available at: https://www.garant.ru/products/ipo/prime/doc/400799739/ (accessed: Aug. 12, 2021); order No. 3 of the chief public health officer of Moskovskaya Oblast'. June 16, 2021. "On Prophylactic Vaccination of Certain Vulnerable Population Groups." Available at: https://rg.ru/2021/06/16/mosobl-post3-reg-dok.html (accessed: Aug. 12, 2021)

the current pandemic's influence on the classical socio-economic order — and, therefore, legal order — appears to be exceptionally vast, multi-dimensional, and diverse.

1. The human right to health protection and medical assistance in the framework of human rights

Health in modern world is the supreme, foremost public good, and its importance is so great that its disappearance may render meaningless many other public goods. Besides, people's health is an element of the national safety framework in any state, which accounts for the special protection it enjoys and for its special legal regulation via relevant legal mechanisms.

The right to health protection and medical care, together with other rights, such as, for instance, the right to decent living standards, education, housing, work, social security and protection, form a single harmonious system of people's social rights. The right to health protection and medical assistance has all the characteristics and distinguishing features of this category of rights: they are needed in order to satisfy individuals' basic vital needs, the absence of which makes decent living impossible. Besides, this category of rights (in particular, the right for health protection) are the foundation on which the state's social order rests.

The right to health protection and the right to health mean somewhat different things because the right to health is a civil right. The right to health protection is a fundamental right enjoyed by Russian citizens because a separate constitutional provision, in Article 41 of the Russian Federation Constitution, establishes the right to health protection and medical care for every person and it can be argued that this right has some bearing on the state's obligation to protect people's health (enshrined in Part II of the Constitution). In view of the above, these writers subscribe to E.B. Luparev's and E.V. Yepifanova characterization of the state's obligation to protect people's health as "a system including healthcare in a broad socio-organizational sense as the state's activity aimed at ensuring a high level of people's health, as well as the narrowly defined sectoral activity — a system of disease control and prevention measures carried out by healthcare organizations" [Luparev E.B., Epifanova E.B., 2021: 67].

Another implication of the fact that this right is enshrined in the Constitution is that all non-Russian nationals residing in Russia are afforded opportunities to realize the right to health protection on an equal footing with Russian citizens, strictly in agreement with the supranational documents signed by Russia [Lukhtenkova Ya.S., 2018: 187].

This right has an especially noticeable synallagmatic quality, which is a very important function of practically any right: the need to bring into agreement private and public interests.

Now, after a general overview of the right to health protection, the essence of the right and its place in the legal landscape need to be addressed in more detail.

When this right is accorded the constitutional status, it is recognized as a foremost public good and value in the system of public goods and values, which forms the backbone of any social order; but this status also has another implication — the state assumes obligations to ensure and enforce this right since any state's preeminent mission is to prioritize this right as an essential human and civil right.

It follows from the above that if the right to health protection is established as a basic constitutional civil right, the state then is obligated to create an environment and a socio-economic system that are fit for the purpose and, taken together, would enable people to maintain, recover and strengthen their health. The latter aspect is one of the foremost and most valuable social goods for any person, irrespective of his/her ethnicity, religion, social position, etc. [Mironova O.A., 2018: 107].

Sure enough, the state's performance in meeting its obligations mentioned above depends on a great number of factors, the most vital among which are arguably political, economic, and cultural factors.

Perhaps it would not make sense to debate the significance of the above mentioned factors since each of them can either raise a country's living standards on the basis of this right or, to the contrary, turn these state obligations in a mere legal formality with no material basis. One of good examples of the latter is a situation of political instability (civil war), which significantly weakens the right to, and guarantees of, health protection, not to mention the impossibility of fully guaranteeing the right to life typical for such situations.

And when levels of economic development and social security in a country are low, economic factor has a significant impact on the level of medical care, which is what is happening now with medical care in the regions. When the situation in a country is unstable and the level of economic development is low, the financing of the country's healthcare institutions becomes reduced to a bare-bones minimum, the way it happened, for instance, in the 1990s.

Such indicators as the population's knowledge levels and its awareness of the themes and issues related to the protection of its own health are like-

wise some of the fairly important factors that prevent living standards from slipping. And the lack of knowledge causes non-compliance with disease control and prevention norms, the spread of various transmissible diseases, bad habits, etc. The factors at the other end of the spectrum include strong awareness levels among the country's population, a strong economy and a facilitative political environment — taken together, they empower the state to competently fulfill its obligations with respect to ensuring guarantees for realizing the right to health protection and medical care.

As mentioned above, enforcing the right to the highest level of health, which is enshrined, inter alia, in the international human rights documents, belongs to everyone and depends on a very wide range of socio-economic and political factors that create the environment beneficial for people's health. According to the Russian legislation, these factors include neither more nor less than acceptable and safe labor conditions, quality medicines, and medical assistance accessible to all.[3]

The right for health protection and medical care, as well as components of this right, are enshrined in numerous federal legal acts of the.

If we look specifically at healthcare organizations affiliated with the International Medical Cluster, their functioning is regulated by Federal Law No. 160-FZ of June 29, 2015 "On the International Medical Cluster and Introducing Amendments to Certain Legal Acts of the Russian Federation"[4].

Summarizing the above, it seems safe to conclude that the constitutional right to health protection is quite an elastic concept, and yet, the process of realization of this right is fairly well detailed, so a thorough knowledge of this legal aspect enables one to competently adopt and implement measures for realizing this right in Russia.

The Constitution is the cornerstone of the country's legislation, as well as the foundation of the nation's current healthcare system. Absolutely every sector and sphere of the national legislation starts off with sections, chapters and articles of the Constitution. This is spheres of economy, taxation, social security, and law enforcement, as well as several other legal spheres.

Issue-specific legal acts elaborate on the articles of the Constitution, providing a more in-depth treatment to every aspect of health protection

[3] The Labor Code of the Russian Federation. Federal Law No. 197-FZ. Dec.30, 2001; as amended June 28, 2021. Compendium of Laws of the Russian Federation. Jan. 7, 2002. No. 1. Art. 3.

[4] Federal Law No. 52-FZ June 29, 2015 "On International Medical Cluster and Introducing Amendments to Certain Legal Acts of the RF" (as amended on July 26, 2019). Compendium of Laws of the RF. July 6, 2015. No. 27. Art. 3951.

and the delivery of medical care. Thus, for instance, several federal laws regulate and define:

the initiation and evolvement of relations in the area of the state's oversight of disease control and prevention; organization of the state's disease control and prevention service; prescription of various sanctions for unlawful acts in this field[5];

conceptual / notional framework. In particular, much attention is paid to defining such important concepts as medical intervention, a medical service, medical care, health protection, "health" as such, etc. A list of health protection principles including such important ones as the absence of the option of turning down medical assistance, quality and accessibility of medical assistance.

If it has been established that a medical intervention is necessary and ought not to be delayed, the law establishes conditions under which the consent of the patient or his/her legal representative can be dispensed with. Such conditions include illnesses that can be dangerous for people other than the patient; severe mental disorders; the patient's criminal record[6].

There are other federal laws, which, firstly, make the state responsible for containing the spread of HIV infections in Russia. The law makes the executive organs and organs of local self-government responsible for fulfilling this obligation[7]. Secondly, the federal laws provide legal regulation of national policies to contain and combat tuberculosis, first of all for the purposes of health protection, disease and control prevention, and for other purposes[8].

The healthcare reforms in Russia produced an array of legal acts related to health insurance: this proves the need to legislatively regulate social measures of disease control and prevention.

Law does not establish an order in which problems related to reproductive health should be regulated. This problem is presently very important

[5] Federal Law No. 52-FZ. March 30, 1999. "On Healthcare and Epidemiological Control" as amended on July 2, 2021. Compendium of Laws of the RF. April 5, 1999. No. 14. Art. 1650.

[6] Federal Law No. 323-FZ Nov. 21, 2011 "On the Basics of Health Protection in the RF" as amended on July 2, 2021. Compendium of Laws of the RF. Nov.28, 2011. No. 48. Art. 6724.

[7] Federal law No. 38-FZ March 30, 1995 "On Prevention of HIV in the RF" as amended on July 2, 2021. Compendium of Laws of the RF, April 3, 1995. No. 14. Art. 1212.

[8] Federal Law No. 77-FZ July 18, 2001 "On Prevention of Tuberculosis in the RF" as amended on May 26, 2021. Compendium of Laws of the RF. June 25, 2001. No. 26. Art. 2581.

for our society because it is closely related to several others: demographic problems, family problems, problems of sterilization and castration, polls about sperm donation [Sivochalova O.V., Lineva O.I. et al., 2017: 39].

2. Some comments on the place of biomedical law in Russia's legal space

Presently biomedical law is just a theory, although federal lawmakers have been seriously contemplating the introduction of this new branch of law.

These writers expect that this branch would rest on a foundation of integrated studies combining legal and other disciplines. Presently there exists a vital need in such branch of law as healthcare law, but in order to qualify as a branch, healthcare law needs some fine tuning, in relation to legal science, the vast pool of medical knowledge, and ethics.

The state should realize that a biotechnological world order is irreversible and the body of law should be developed fast lest we find ourselves on the sidelines of the quickly evolving processes [Sokolova N.V., 2018: 89]. So these writers consider it necessary to introduce amendments to the federal legislation that would be in line with the rapid progress in biotechnology [Savoshchikova E.V., Gurnaya L.E., 2018: 219].

The subjective right to health in the framework of constitutional human rights and freedoms is distinctive because a state of health as such is one of the factors that have the greatest impact on every person's everyday living. Such problems as a poor health or various physical disabilities usually produce a negative effect on an affected person's way of living — they can limit such person in his/her choice of a profession or a school, sports or cultural activities, a religion, a place of residence; they can limit the affected person's options in terms of the exercise of main personal rights (e.g., freedom of movement) [Lastovetsky A.G., Kitanina K.Yu., Khromushin V.A., 2019: 76].

Establishing the right to health protection, the state, according to Article 41(2) of the Constitution, assumes the obligation to ensure protection of its citizenry's health, irrespective of the factors mentioned above, as well as protection of citizens residing or sojourning abroad on account of the international legal acts (for instane, the diplomats).

This article also defines the federal healthcare system, thus contributing to the constitutionalization of the right at issue.

According to Article 41 of the "Basics of Health Protection", the foundation of the state healthcare system is comprised of the following:

federal executive organs responsible for health protection and their territorial organs;

executive organs of the constituent entities / regions responsible for health protection, healthcare administrations of other federal executive organs (except federal executive organs referenced in para 1);

organizations under the aegis of federal executive bodies, state academies of sciences, and executive organs of the constituent entities: medical and pharmaceutical bodies; healthcare bodies responsible for supervision of consumers rights protection and human welfare; forensic science institutions; other bodies and their non-local subsidiaries engaged in health protection[9].

The non-public healthcare system is usually comprised of medical care institutions which are organized by individuals or corporate entities and which contribute to ensuring people's right to health protection.

In the national and municipal healthcare systems citizens are already provided with medical assistance free of charge. The article of the Constitution quoted above references citizens as sole recipients of free-of-charge medical assistance. As for foreign nationals and stateless persons, Russia assumes an obligation to provide them with medical assistance in keeping with the Russian national healthcare standards set forth in order No. 186 of the Russian Federal Government, March 6, 2013 [Medvedeva O.V., Afonina N.A., Draenkova F.R., 2017: 21].

3. Institutional underpinnings of the right to health protection at supranational level

According to a human rights theory well known in international scholarship, even a formally established right creates an obligation for the state.

In the area under review, legal norms related to the state's positive obligations require active reciprocated interactions because in a globalized environment many legal issues, as well as some of the challenges related to human rights, can be handled only cooperatively.

From the standpoint of supranational law, the authority analyzed here also implies facilitating the improvement of population's health and living standards.

[9] Federal Law No. 73-FZ May 31, 2001 "On State Forensic Expertise in the RF" as amended on July 1, 2021. Compendium of Laws of the RF. June 4, 2001. No. 23. Art. 2291.

The institutionally anchored component, comprised of organizations participating in international healthcare cooperation, has three levels.

The first level is global. It includes global healthcare organizations.

The second level includes governmental and non-governmental organizations. They cooperate with each other over legal issues of healthcare, performing certain tasks in separate regions.

The third level is national healthcare agencies.

This level also includes such organizations as the International Red Cross and Red Crescent Movement.

The above organizations may be characterized as subjects of international cooperation.

Having addressed the third level of organizations, one can now proceed to review the constitutional right to health protection in the Commonwealth of Independent States and Russia in particular.

So, in the Russian legal system, healthcare is pivoted on a well-established hierarchy issuing from Article 41 of the Constitution.

The right to health protection, therefore, is hierarchichlly structured: the Constitution is the supreme law and it also anchores this right in subordinate legal acts [Tuchkova E.G., 2017: 60].

Given all of the above, it would seem safe to conclude that the right to health protection is quite securely established at the constitutional level in the RF, thanks to which the Russian legislation can be easily adapted to different healthcare challenges, and it is likewise solidly established at an international level, where efficient international organizations are comprised of member states that have more or less similar constitutional provisions with respect to the right at issue and, as a result, a consensus can be reached fairly easily.

4. The mandatory nature of the vaccination requirements issued by the chief public health officer and the scope of their application

During the COVID-19 pandemic special importance is attached to bylaws issued by chief public health officers of the RF and its regions because of these officers' legal status and core competence. So, an important question today is whether the requirements set forth in the public health officers' orders are imperative or non-binding for the addressees. The following pivotal points need to be emphasized:

Firstly, presently the anti-COVID vaccinations are smoothly integrated into the vaccination schedule. Moreover, there were plans to include them into the national vaccination schedule. In particular, this proposal was set forth in draft law No. 1179765-7[10], initiated by the federal government; the draft was passed by the Duma at the first reading but on June 15, 2021 it was voted down by the lower house and removed from the legislative agenda. These writers believe that the majority of the Duma's deputies were absolutely right rejecting this draft law because presently in Russia the COVID-19 vaccination remains voluntary, as required by the Russian law, despite certain exceptions to the rule.

Secondly, federal law No. 157-FZ Sept. 17, 1998 "On Immunoprophylaxis of Transmissible Diseases" contains a provision authorizing mandatory epidemiological situation in the RF becomes sufficiently bad, this law allows to prophylactically vaccinate Russian citizens.

And thirdly, federal law No. 52-FZ March 30, 1999, in Article 51(6), allows to regional chief public health officers and their deputies to issue bylaws (orders) on prophylactic vaccination of the entire population or specific population groups in regions within their purview. The only condition that must be met before the introduction of a mandatory vaccination regime is the presence of an objective risk of Russian citizens contracting transmissible diseases.

So, regional chief public health inspectors obviously have the right, enshrined in federal legislation, to issue orders about mandatory vaccination during a pandemic.

According to order No.1 issued by Moscow's chief public health officer on June 15, 2021, and order No.3 issued by the chief public health officer of Moskovskaya Oblast' on June 16, 2021, there are two main categories of persons who must be vaccinated: the first category includes staff members employed under employment contracts or independent contractor agreements by sole traders and corporate employers in fields listed in the orders (hereinafter referred to as staff members, independent contractors or, when the distinction does not matter, as jobholders). These writers use here the term "independent contractors" in line with the orders' terminology — the term refers to persons employed under independent contractor agreements by sole traders or corporate entities.

It should be pointed out that the vaccination requirement applies first of all to jobholders in businesses-to-consumer (B2C) services sectors. Interest-

[10] Draft law No. 1179765-7 "On Introducing Amendments to Art.9 of the Federal Law 'On Immunization Against Transmissible Diseases.'" Available at: URL: http://www.consultant.ru/cons/cgi/online.cgi?req=doc&base=PRJ&n=207896 (accessed: Aug. 17, 2021)

ingly, "commerce", listed in the order, does not contain a reference to retail — in other words, from a formal point of view, the order equally applies to sellers dealing with corporate entities. But such interpretation, in these writers' opinion, does not conform with the orders' goal, which is to ensure epidemiological safety for people who directly come into contact with jobholders at B2C services organizations. These writers, therefore, consider that the reference to commerce in the order should be interpreted as retail commerce. That said, one hopes to see in the nearest future an official clarification that would eliminate the risks of multiple interpretations of the text of the orders.

The second category includes public servants at national and municipal agencies in Moscow, as well as employees of Moscow's administration and its subordinate entities.

5. Obligations and responsibility of employers in the context of the vaccination campaign

Pursuant to the orders issued by chief public health officers of Moscow and Moskovskaya Oblast', corporate entities and sole traders working in the fields listed in the orders must do the following:

to organize a two-stage vaccination campaign. The first stage, prior to July 15, 2021: administering the first dose; the second stage, prior to August 15, 2021: administering the second dose, to as least 60% of jobholders.

A literal interpretation of the order suggests that the baseline for determining 60% is the total headcount of jobholders. The total count includes:

staff members and independent contractors;

adults as well as minors (of less than 18 years of age);

both unvaccinated persons (including persons with contraindications to vaccination) and persons already vaccinated;

jobholders whose duties are related to the lines of work listed in the orders and jobholders whose duties are not related thereto. These writers doubt the expediency of the latter requirement. However, lacking specialized knowledge in the area of epidemiology, they would recommend to rely on the literal interpretation of the orders' text.

So it is 60% of the overall number of jobholders that have to be vaccinated. In these writers' opinion, the orders' texts imply that individuals who became vaccinated independently of their employers can be included into the quota. The most essential thing is to ensure that 60% of all job-

holders are vaccinated. The odds are, however, that the authorities may still insist that the reference headcount for 60% is still unvaccinated jobholders. For all that, it should be kept in mind that in any case an individual must give a voluntary, unforced consent to the medical intervention before being vaccinated.

It is thus up to jobholders themselves to decide whether to consent to the vaccination and they have the right to turn this option down. Corporate entities and individual entrepreneurs have no right to introduce any sanctions against jobholders who refuse to become vaccinated. Employers' options are limited to the following:

energizing efforts to educate their staff members, independent contractors about the need to observe the existing disease control and prevention norms designed to prevent COVID-19, emphasizing the need for vaccination as the key factor in the struggle against the disease.

The orders do not reference specific measures in relation to the administration of the prophylactic vaccines, so this is left to employers' discretion. One would assume that employers are expected to subcontract vaccination to healthcare providers and to afford their staff members, independent contractors the opportunity for the vaccination (grant them a release from work). Other measures can be applied as well: incentives such as bonuses, an additional day off work, etc.

The RF has the general rule that prophylactic vaccinations included in the official immunization schedule are provided free of charge for individuals who are being vaccinated. So, when staff members, independent contractors have mandatory health insurance policies and their employers organize a vaccination at a federal / municipal healthcare institution, they are not charged for the vaccination.

As for the COVID-19 awareness raising, it can include both verbal and written methods (hand-to-hand distribution / mailing of information leaflets, printouts, etc.) and can be carried out either by the employer or experts (doctors, medical researchers, etc.).

Moscow's mayor and the governor of Moskovskaya Oblast' imposed additional obligations on employers: in the period July 1-15, 2021 they had to submit reports about their implementation of the chief public health officers's requirements; these reports had to be submitted electronically, via employers' electronic accounts — in Moscow, on the site of the mayor and government of Moscow, and in Moskovskaya Oblast', on the regional portal of public services.

If an employer fails to comply with the mandatory vaccination requirements set forth in the chief public health officers' orders, this employer, in these writers' opinion, may be in breach of Article 6. 3(2) of the Code of Administrative Offences (CAO). And if an action (inaction) causes someone's death or harm to someone's health, the offender is liable under Art. 6.3 (3) of CAO providing for more serious penalties.

At the core of every administrative offence, however, is the offender's culpability. It needs to be pointed out that a corporate entity / sole trader can be held charge with an administrative offence only when it has been established that this entity / sole trader was able to observe the norms and rules whose breach qualifies as an administrative offence but for some reasons deliberately neglected to use all methods and instruments at its disposal to ensure a full compliance. So, if an employer takes all necessary steps to ensure the vaccination and raise its jobholders' awareness of the issue but jobholders turn down the vaccination offer, this employer cannot be charged with an administrative offence on account of the failure to reach the 60% vaccination threshold as required in the orders.

It would appear advisable to document measures implemented to organize the vaccination and raise jobholder's awareness, and to obtain written refusals from jobholders who refuse to be vaccinated.

An employer's failure to fulfill the requirement, set forth in the orders, to submit the report electronically can be classified as an offence under Art. 20.6.1(1) of the CAO.

As for administrative sanctions against individuals who refuse to become vaccinated, these writers consider that it is impossible to apply any since individuals' right to turn down an offer of a vaccine is unconditional.

6. Consequences of a jobholder's refusal to become vaccinated

The Labor Code obligates employers to suspend jobholders from job duties or to withhold from them access to the workplace in some cases, as provided for, inter alia, in other federal laws and bylaws. It should be also noted that under Art. 76 (3) of the Labor Code, in the period when a jobholder is thus suspended from his/her duties, the employer has the right to withhold his/her pay for that period.

In particular, the following fact can be highlighted: federal law No. 157-FZ Sept.17, 1998 "On Immunization Agains Transmissible Diseases" indeed

contains a provision which, one the one hand, allows potential employers to turn down unvaccinated job seekers, and on the other, allows employers to suspend unvaccinated staff members from their job duties[11]. It should be remembered, however, that this norm applies only to those staff members whose professional duties expose them to a high risk of transmissible diseases. The list of such lines of work was compiled and officially approved by the federal government[12]. So, the employer arguably must suspend from duties (refuse to hire) individuals who refuse to become vaccinated only if the job at issue is included in the list of jobs exposing jobholders to a high risk of contracting transmissible diseases. Such measures may not be applied to staff members in other lines of work.

As for independent contractors, when such jobholder refuses to become vaccinated, a theoretically viable option would be raising the question of terminating the agreement on account of material changes in circumstances. These writerw wish to point out, however, that given the absence of a provision prohibiting hiring unvaccinated individuals under independent contractor agreements it seems unreasonable to argue that the circumstances have changed so greatly that had the parties been able to foresee such changes they would not have entered into the agreement or would have entered into an essentially different agreement; an independent contractor's refusal to become vaccinated, therefore, is not to be regarded as a material change of circumstances. Other implications in case of a refusal to become vaccinated, meanwhile, may be provided for in independent contractor agreements.

Conclusion

The experience of struggle against COVID-19 in different countries shows that in emergencies constitutional rights of individuals can be restricted and applied selectively, which calls into question the principle of equality of all before the law and equality of individuals' rights. The efficiency of legal regulation in this field and the controversial aspects of the application of law leave little doubt that the relevant regulatory frameworks have problematic aspects.

[11] Federal law No. 157-FZ Sept.16, 1998 "On Immunization Against Transmissible Diseases" as amended on July 2, 2021. Compendium of Laws of the RF. Sept. 21, 1998. No. 38. Art. 4736.

[12] Order No. 825 of the Government of the RF (July 15, 1999) "On Approving the List of Jobs Which Expose Jobholders to High Risk of Contracting Transmissible Diseases and Require Prophylactic Vaccination" as amended on Dec.24, 2014. Compendium of Laws of the RF. July 19, 1999. No. 29. Art. 3766.

According to the spirit of the modern civilizational theory, the right of an individual to health protection and medical care does not line up with the trajectory of individualism — rather, it becomes a composite value of any state and civil society. This right is singular because individuals do not obtain it over the course of their lives but have it since the moment of their birth, so this right cannot be taken away from them. Besides, this right implies that individuals should take adequate care of their health and, also, that the state should prioritize health needs of its citizens.

Two most important federal regions — Moscow and Moskovskaya Oblast' — became key drivers in the Russian national campaign of mandatory COVID-19 vaccination[13]. They largely charted the course of administrative and legislative regulation of this process, and their positive experience was adopted by other regions.

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[13] The best practices of Moscow and Moskovskaya Oblast' in the field of implementation of the mandatory vaccination program has now been adopted by all regions. The regions have followed the suit of Moscow and Moskovskaya Oblast': first, the regions' chief public health inspectors issued the relevant orders; second, the authorities designated groups to be vaccinated; third, the authorities established timelines for administering the first and the second doses of the vaccine or the single-dose vaccine. Available at: URL: http://ivo.garant.ru/#/document/77311703/paragraph/1:0 (accessed: Oct. 27, 2021)

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Comment

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Review of Key Positions of the Presidium of Intellectual Property Court of the Russian Federation

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Abstract

The comment reviews key positions issued in the rulings of September and October 2021 by the Presidium of the Russian Intellectual Property Court (IPC). This Chamber hears cassation appeals against the decisions of the IPC first instance and deals primarily, but not only, with matters of validity of registered intellectual property rights. Therefore, this review primarily deals with substantive requirements for patent and trademark protection, as well as with procedural issues both in the administrative adjudicating mechanism at the Patent office (Rospatent) and at the IPC itself. The current review covers such issues as appeals against patent term extension (supplementary patent), appeals against partial refusals of trademark applications, distinctive character of trademark elements, a party's interest in judicial proceedings on unfair competition involving trademarks, and conflicts between trademarks and company names.

Keywords

Russia, case-law, Intellectual Property Court, Rospatent, supplementary patent, trademarks, company names, unfair competition, procedure

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1. Contesting supplementary patent

A supplementary patent certifying the extension of the term of validity for an exclusive right, which has been granted in violation of the conditions stipulated in Art. 1363, para. 1(2) of the Civil Code of the Russian Federation (CC RF), may be contested in the Intellectual Property Court by an interested person on the basis of Art. 1398, para. 1(1) of the CC RF.

Decision of the Presidium of the IPC dated 18 October 2021 in case No. SIP-461/2020.

At present in accordance with Art. 1363, para. 2(1) of the CC RF, in the event that more than five years have elapsed from the date of filing a patent application for an invention related to such products as medications, pesticides, or agro-chemicals whose use requires obtaining permission through a procedure established by law, then the term of validity for exclusive rights to such an invention and of the certification of the right of patent is to be extended upon the application of the patent holder to the federal executive authority for intellectual property (Rospatent).

Pursuant to the current version of Art. 1363, para. 2(5) of the CC RF, upon extension of the term of validity for an exclusive right, a supplementary patent is to be issued in a format which includes all the features of the patented invention which are characteristic of the product for which permission to use the invention has been obtained.

Therefore, the basis for considering issuance of a supplementary patent is the application of the patent holder; however, the conditions for issuing it (i.e. extension of legal protection for a particular product) include:

a product such as a medication, pesticide, or agro-chemical whose use requires obtaining permission though a procedure established by law with that permission protected by a patent on an invention (hereinafter basic patent);

permission for the use of that product;

absence of any prior permissions to use that product;

expiration of more than five years from the date of filing for issuance of the basic patent until the receipt of such permission.

Pursuant to the current version of Art. 1363, para. 5 of the CC RF, a supplementary patent may be deemed invalid on the grounds and through the procedure stipulated in Art. 1398 of the CC RF.

In accordance with Art. 1398, para. 1(1) of the CC RF, a patent for an invention, utility model, or industrial design may be deemed invalid in its entirety or in part, including in the event that the invention, utility model, or industrial design does not conform to the conditions for patent eligibility as prescribed by the CC RF.

The general conditions for an invention to be eligible for a patent apply both to the invention under the basic patent and also to the product under the supplementary patent and are stipulated by Art. 1350 of the CC RF. In addition, Art. 1363, para. 2(1) specifies the conditions for issuing a supplementary patent and also identifies the potential legal protections for a product under a supplementary patent. However, the legislature has not made the provisions of Art. 1398, para. 1(1) of the CC RF consistent with Art. 1363, para. 5 of the CC RF. Art. 1398, para. 1(1) does not take into account the possibility of contesting supplementary patents, nor does it acknowledge that such patents are subject to special conditions for their issuance pursuant to Art. 1363 para. 2(1) of the CC RF.

Art. 1363, para. 5 of the current CC RF indicates that a supplementary patent is subject to contestation on the grounds specified by Art. 1398 of the CC RF, but no such grounds are stated in Art. 1398 of the CC RF. Art. 1398, para. 1(1) of the CC RF is applicable to a supplementary patent merely to the extent that the basic patent may be contested; however, in breach of Art. 1363, para. 5 of the CC RF, no grounds for contesting a supplementary patent as such are specified. This situation indicates a gap in legislative regulation (Art. 6 of the CC RF) with respect to the grounds for contesting supplementary patents.

Issuance of a supplementary patent affects third parties that may have a private interest in using a technical solution after the expiration of the statutory term of validity for a basic patent, and it has an impact on an indefinite group of persons by impeding scientific advances and the activities of third parties in employing technical solutions that have devolved into the public domain. Issuance of a basic patent has the same consequences.

The public interest lies in ensuring that unlawful issuance of patents does not impede scientific advances or usage by third parties of technical solutions which are not eligible for protection, and that interest persists so long as the patent remains valid or may possibly be renewed. In that sense,

the ability to contest an unlawfully issued supplementary patent has the same significance as the ability to contest a basic patent because a supplementary patent extends the term of the basic patent as it applies to a product covered by an invention under the basic patent.

As already noted above, the legal significance of the general conditions for eligibility of inventions (Art. 1350 of the CC RF) and the special conditions for eligibility of a product as such for a supplementary patent (Art. 1363, para. 2(5) of the CC RF) are identical — and both stipulate the conditions for a patent and for the term of its validity. Hence, the legal relations that arise from these legal standards are analogous.

The ability to contest supplementary patents is not only not in conflict with the essence of those relations but also explicitly stipulated by current law (Art. 1363, para. 5 of the CC RF). Consequently, the Presidium of the Intellectual Property Court is maintaining that a supplementary patent issued in violation of Art. 1363, para. 2(1) may be contested; by analogy, the applicable laws are Art. 6 (1) and Art. 1398, para. 1(1) of the CC RF.

The ability to verify the conformity of a supplementary patent with the special conditions for its issuance (Art. 1363, para. 2(1) of the CC RF) is guaranteed by Art. 46 of the Constitution of the Russian Federation and may not be restricted precisely because the law does not indicate special grounds for such verification.

Eurasian patent legislation (which in general has been harmonized with the internal legislation of the Russian Federation) follows the same approach, which stipulates the procedure for contesting the term of validity of a patent but not for contesting the actions of the Eurasian Patent Office in prolonging the validity of a patent.

Hence, in accordance with Regulation 16, para. 7(a) of the Patent Instructions for the Eurasian Patent Convention (adopted 1 December 1995), after the date of public notice of extension of the term of a patent until the date of expiration of that term, any person may submit an objection to the Eurasian Office concerning extension of the term of a Eurasian patent on grounds of non-compliance with the conditions for extending the term of the patent as stipulated by the legislation of a Contracting State applicable to extension of the term of a Eurasian patent. Regulation 16, para. 7(b) of the Patent Instructions for the Eurasian Patent Convention establishes that the outcome of considering an objection may be a decision either to annul the extension of the term of a Eurasian patent or to dismiss the objection. Although the grounds for contesting supplementary patents are omitted

from legal regulation, there is no omission of the procedure for such contestation.

In accordance with Art. 11, para. 1 and Art. 1248, para. 1 and 2 CC RF; in the event that the law does not provide an administrative procedure for considering a particular dispute concerning an item of intellectual property, a judicial procedure is to be applied. Therefore, in the absence of any direct legal standard pertaining to an administrative procedure for the protection of civil rights, a judicial procedure for their protection is to be applied.

Pursuant to Art. 43.4 (2)(2)(5) of the Federal Constitutional Law dated 28 April 1995 No. 1-FKZ "On the commercial courts of the Russian Federation" and Art. 4 (2)(5) of the Commercial Procedural Code of the RF, the competent court for considering such disputes is the Intellectual Property Court. Such a dispute may be considered upon the application of an interested party (Art. 4 of the Arbitration Procedural Code of the RF).

The Presidium of the Intellectual Property Court noted that the contested patent had been extended while the previous version of Art. 1363 of the CC RF, under which no supplementary patent had been issued, was in force, but the term of validity of the basic patent was extended for a specific product. Nevertheless, there was no difference in the essence of the relationship, and there was also a gap in the legislative regulation for contesting an unlawful extension of legal protection for a specific product covered by a patent. The conditions for extending the term of a patent in Art. 1363, para. 2 of the CC RF were the same, and contesting the validity of an exclusive right (including its extension) was allowed to proceed in the same manner as in para. 5 of that article of the Code. Art. 1398, para. 1(1) CC RF also did not take into account the fact that additional conditions had been established for legal protection of the product whose legal protection had been extended.

In view of the above and with regard to the previous version of the CC RF, the Presidium of the Intellectual Property Court concluded that the product's legal protection, which had been extended in violation of the conditions of Art. 1363, para. 2(1) CC RF may be contested; by analogy the laws also applicable are Art. 6(1) and Art. 1398, para. 1(1) of the CC RF.

2. Contesting the decision of Rospatent to reject in part the registration of a trademark

The fact of registration of a trademark with respect to a portion of the goods and services for which application has been submitted does not con-

stitute an obstacle to contesting a decision of Rospatent based on Art. 1500 of the CC RF as it pertains to rejection of registration of a trademark for other stated goods and services for which application has been submitted.

Decision of the Presidium of the IPC dated 15 October 2021 in case No. SIP-139/2021.

Rospatent reached a decision to register a trademark with respect to a portion of the goods and services for which an application had been submitted and to reject registration for the remainder of the goods and services. The applicant contested this decision to reject registration, but Rospatent refused to consider the contestation. Rospatent's reasoning based on a combined reading of Art. 1500 and 1512 of the CC RF was that Art. 1500, para. 1 of the CC RF governs only the procedure for contesting a decision on state registration of a trademark on the condition that state registration had not yet taken place, but in this instance state registration of a trademark had already taken place at the time the contestation was advanced.

The decision of the Intellectual Property Court, which was upheld without change by the Presidium of the IPC, was that Rospatent had acted unlawfully, and the Court required that administrative body to consider the applicant's contestation.

The Presidium of the IPC noted that Rospatent's decision concerning state registration of a trademark for only a portion of the goods and services for which application had been submitted in fact consisted of two parts: a decision to register a trademark for a range of goods; and a decision to reject registration of a trademark for the remainder of the goods and services. The first decision, which granted an exclusive right to the applicant, may be contested by a third party through the procedure set in Art. 1512 and 1513 of the CC RF. The second decision, whose outcome was that no exclusive right was granted, may be contested by the applicant through the procedure in Art. 1500 of the CC RF.

When an applicant is objecting to the partial rejection of registration of a trademark, invoking Art. 1512 and 1513 of the CC RF would be in error for several reasons: those articles do not specify any grounds for the actual rightholder to contest the decision; those grounds do not apply to broadening legal protection but merely to annulling it or restricting it, and in general the provisions of Art. 1512 of the CC RF may not be applied to restoration of rights which the possessor of a right regards as infringed.

Pursuant to Art. 1500 of the CC RF, the right to contest by submitting to an administrative body a challenge of a decision by Rospatent to reject

registration of a trademark is restricted solely with respect to the deadline for submission of such a challenge (four months from the date of issuance of the decision). Any other restrictions on the right to a timely contestation would be groundless. Hence, Rospatent's reference to Regulation No. 644/261, para. 13 in rejecting a contestation due to the existence of state registration of a trademark was without merit. The opinion of the Presidium was that this point presupposes the existence of state registration explicitly for specific goods and services and not of registration as such, and it does not stipulate its application to the "rejecting" portion of a decision concerning state registration of a trademark. The Presidium noted also that payment of the state fee for registration of a designation for which an application had been submitted with respect to a portion of the goods and services does not constitute grounds for rejecting consideration of a contestation of the rejection to register the designation applied for with respect to other goods and services on the basis of Art. 1500 of the CC RF. Payment of the state fee does not indicate agreement with the decision of an administrative body concerning rejection of registration of a trademark and does not impair the right to appeal such a decision.

3. Establishing the distinctiveness of the elements of a trademark

If Rospatent has recognized that certain designated elements are distinctive of the goods and services for which an application has been submitted, then it is bound by its findings with regard to registration of those same elements by that same applicant. In the absence of challenges from other parties, the elements that have at a certain time been recognized by Rospatent as being distinctive must thereafter be recognized by that administrative body as having that quality.

Decision of the Presidium of the IPC dated 4 October 2021 in case No. SIP-1047/2020

Rospatent rejected registration as a verbal trademark of a designation consisting of the elements ONE, PRICE, COFFEE on the grounds that the designation was not distinctive (Art. 1483, para. 1 of the CC RF). Rospatent arrived at the conclusion that this designation could be interpreted as an indication that the field of activity of the applicant connected with particular goods and services (coffee, coffee-based products, and products with a coffee aroma, as well as services to make and sell coffee at a single price or to provide coffee at a single price) and that it characterizes the goods and services which are to be individualized by the designation.

However, an analogous combined designation had previously been registered by Rospatent as a trademark for services, including for the very same services that were applied for in the disputed designation, and therefore its distinctiveness had been recognized.

With regard to this, the Presidium of the IPC noted that, in registering other trademarks from the same party, the administrative body was bound by its findings concerning the identical elements in those trademarks. In the absence of challenges from other parties, the elements that had at a prior time been recognized by Rospatent as being distinctive must thereafter be recognized by the administrative body as having that quality.

The finding that any element of a trademark lacks distinctiveness (or that the trademark as a whole lacks distinctiveness) may be reconsidered by Rospatent exclusively through the procedure established by the CC RF for considering administrative appeals. Any other treatment would not comply with Art. 45 (1) of the Constitution of the Russian Federation.

Furthermore, the Presidium noted that the evaluation of a designation in accordance with the requirements of Art. 1483, para.1 of the CC RF must proceed from its understanding by a typical, average consumer of such goods in the Russian Federation, who is the target audience of the goods for which individualization by a trademark has been requested. The Presidium therefore deemed erroneous the reliance of the court of first instance on the opinions of persons with specialized knowledge of design and art history in evaluating the understanding of the designation. In view of the foregoing, the case was referred for reconsideration to the court of first instance.

4. Interest in litigation of cases pertaining to unfair competition

Legal positions concerning the interest of a plaintiff in disputes concerning trademark cancellation for lack of use are not applicable either directly or by analogy with cases pertaining to claims that acquisition of exclusive rights to a trademark constitutes unfair competition.

Registration of a trademark by a party which is affiliated to other parties whithin a group and determination among those parties themselves of the procedure for exercising the exclusive rights to that trademark is a customary commercial practice. In order to find that such a customary commercial practice is unfair, the purpose of the pertinent acts and the aim of that party's conduct must be proven.

Decision of the Presidium of the IPC dated 4 October 2021 in case No. SIP-4/2021.

The plaintiff filed a judicial action claiming that the acts of an affiliated party in acquiring and exercising exclusive rights to a trademark for identical goods constituted unfair competition under the provisions of the Federal law on the protection of competition of 26 July 2006 No. 135-FZ, as well as abuse of rights.

The decision of the Intellectual Property Court, which was upheld without change by a decision of the Presidium of the IPC, rejected the claims. The cassation appeal was rejected due to the plaintiff's lack of an independent interest in that category of cases or of the right to an indirect claim on protection of the interests of the legal entity in which the plaintiff was a participant.

In cases pertaining to unfairly obtaining and using a trademark, current legislation does not grant a right of indirect appeal to a participant in a legal entity. With respect to the interest of that party itself, the Presidium of the Court emphasized the distinction between the essence of the legal relations incorporated in antimonopoly legislation regarding unfair competition through registration of a trademark and those pertaining to an trademark cancellation action for lack of use (Art. 1486 of the CC RF). The latter does not take into account the purpose of rightholder in registering a disputed trademark, and the interest of the plaintiff lies solely in the future. These distinctions bear on the divergent ways in which a trademark dispute may arise for each of the categories, and the legal positions pertaining to disputes on trademark cancellation for lack of use cannot be directly or by analogy applied to disputes concerning improper conduct by a defendant in obtaining and using a trademark. Therefore, the latter category of cases has no bearing on the matter of argumentation concerning the extent of a party's interest in the subsequent use of a disputed trademark, and the point to be proven is the infringement of the plaintiff's rights at the time when the defendant obtained an exclusive right. Analogous positions have been expressed in the decisions of the Presidium of the IPC dated 17 October 2016 in case No. SIP-189/2016, 16 July 2018 in case No. SIP-313/2017, 2 November 2018 in case No. SIP-795/2017, 24 June 2019 in case No. SIP-134/2018 among others.

Concerning the essence of the dispute, the Presidium of the IPC noted that the plaintiff in part grounded their claim that the defendant acted in bad faith on the fact that the disputed trademark had been registered in the name of one of several affiliated legal entities for the purpose of prohibiting use of that designation by another affiliated party. The Court explained that registration of a trademark by one of the parties to an affiliation (and/or

included in a group) and determination among those parties themselves of the procedure for exercising the exclusive rights to that trademark is a customary commercial practice. The intent to prohibit the use of the designation by another affiliated party, for example, in taking action to prevent the use of the disputed trademark did not constitute evidence of ill conduct.

5. Conflict between rights to a trademark and to a trade name

In order to assess whether it is inconsistent in the sense of Art. 1483, para. 8 of the CC RF to register a trademark consisting of a sign previously registered as a company name, the fact of a party's distributing the disputed goods under its own name to the public, in addition to other circumstances, is relevant rather than which party is the manufacturer of the goods. To settle such a dispute would require inquiry into the degree of likeness between the goods for which legal protection of the trademark is being requested and the goods marketed under the company name.

Decision of the Presidium of the IPC dated 20 September 2021 in case No. SIP-937/2020.

The AMAIA, LLC company contested a third party's registration of a combined trademark containing the verbal element "AmaiA" for a range of goods in Class 25 of the International Classification of Goods and Services (clothing). The company alleged violation of Art. 1483, para. 1(3) and para. 8 of the CC RF because the company's registration of its company name had taken place prior to the date of priority for the trademark and because that name was already well recognized in the clothing market. Rospatent dismissed the contestation and made reference to the following: the party bringing the contestation does not manufacture goods of Class 25 of the International Classification of Goods and Services but conducts sales activities that correspond to services of Class 35 of the International Classification of Goods and Services; its retail outlets sell clothing of the foreign brand AMAIA, and the materials presented in the case do not demonstrate any connection between the company and the manufacturer of the clothing.

The decision of the Rospatent was annulled by judgment of the Intellectual Property Court, as upheld by the Presidium of the IPC, on the basis of the following two findings.

First, the Intellectual Property Court stated that the identity of the manufacturer of the clothing sold by the company under its company name has no legal bearing on the proper resolution of the dispute. The Presidium

of the IPC called attention to the set of circumstances that in established practice must be determined in order to resolve the matter of a conflict between registration of a designation as a trademark when there is an opposing company name. The Court noted that the identity of the manufacturer of the products sold under the countervailing company name is not among these circumstances. What is relevant to the matter is the fact itself that the company introduced Class 25 goods, or goods similar to them, into commerce under its company name.

Second, the Intellectual Property Court specified that Rospatent wrongfully declined to investigate the degree of similarity of the clothing sold by the company to goods of Class 25 of the International Classification of Goods and Services, for which the disputed trademark had been issued.

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