Russia

“Remdesivir”

Decision of the Supreme Court of the Russian Federation

27 May 2021 – Case No. AKIII21-303

Russian Constitution, Arts. 2, 17, 18, 55; Federal Constitutional Law of 6 November 2020, Arts. 5, 16, 24; Civil Code of the Russian Federation, Arts. 1229, 1360; Decree of the President of the Russian Federation of 23 May 1996 No. 763; Federal Law of 21 November 2011 No. 323-Ø3 “On the Basics of Health Protection of Citizens in the Russian Federation”, Art. 2

© Max Planck Institute for Innovation and Competition, Munich 2021

Keywords COVID-19 pandemic · Patent waiver · Public health · Emergency situation · Exception · Permission to use · Medicine

1. Article 55, part 3 of the Constitution of the Russian Federation provides for the possibility of restricting rights and freedoms (here patent rights) to the extent necessary for the protection of the foundations of the constitutional order, morality, health, the rights and lawful interests of other people, and for ensuring defence of the country and security of the state.
2. According to Art. 1360 of the Civil Code of the Russian Federation (as amended by Federal Law No. 107-Ø3 of 30 April 2021), the Government of the Russian Federation has the right, in case of emergency related to ensuring the defence and security of the state, and the protection of citizens’ life and health (here due to the COVID-19 pandemic), to decide on utilising an invention, utility model or industrial design without the consent of the patent holder, notifying it of this as soon as possible and paying it proportionate compensation.
3. The amendment by Federal Law No. 107-Ø3 of 30 April 2021 of Art. 1360 of the Civil Code of the Russian Federation by stating that it applies additionally for the purpose of protecting the life and health of citizens, in essence, did not change its previous semantic content.
4. The provisions of Art. 1360 of the Civil Code of the Russian Federation correspond to the provisions of Art. 31 of the Agreement on Trade-Related

Translated from the Russian by Dr. Daria Kim.

Aspects of Intellectual Property Rights (concluded in Marrakesh on 15 April 1994) and are consistent with the Siracusa Principles.

The Supreme Court of the Russian Federation [...] established

On 31 December 2020, the Government of the Russian Federation issued order No. 3718-p (hereinafter “the Order”), according to which Pharmasintez Joint Stock Company is allowed to use inventions protected by Eurasian patents Nos. EA025252, EA025311 and EA029712, owned by Gilead Sciences, Inc. (US), Eurasian patents Nos. EA020659 and EA032239 owned by Gilead Science¹ Inc. (US), as well as Eurasian patent No. EA028742 owned by Gilead Pharmasset LLC (US) (hereinafter – “inventions”, “patents” and “patent holders”, respectively), for one year without the consent of the patent holders to provide the population of the Russian Federation with drugs with an international non-proprietary name “Remdesivir” (point 1²).

[...]

Gilead Pharmasset LLC (US) and Gilead Sciences Inc. (US) (hereinafter “administrative plaintiffs”) lodged an administrative statement of claim with the Supreme Court of the Russian Federation that contests the Order referring to its contradiction with the provisions of Arts. 7, 1229, 1231, 1360 of the Civil Code of the Russian Federation, part 4 of Art. 15 of the Constitution of the Russian Federation, the Eurasian Patent Convention signed on 9 September 1994 in Moscow, and the Convention for the Protection of Industrial Property, signed in Paris on 20 March 1883. According to the administrative plaintiffs, the Order was not adopted in the interests stated in Art. 1360 of the Civil Code of the Russian Federation (the version in force at the time of the Order’s adoption), in the absence of conditions of extreme necessity, for purposes that do not correspond to the goals of ensuring the state security, and therefore unreasonably violates their rights and lawful interests, in particular, causes losses in the form of lost profits related to the production and supply of the drug without the consent of the patent holders.

[...]

[...] [T]he Supreme Court of the Russian Federation does not find the grounds to satisfy the administrative claim.

[...]

The arguments of the administrative plaintiffs that the Order was not adopted in the interests specified in Art. 1360 of the Civil Code of the Russian Federation (the version in force at the time of the Order’s adoption), and contradicts the provisions

¹ Translator’s note: the Eurasian patent database indicates the name of the company as Gilead Science; however, the corresponding PCT applications indicate the name of the company as Gilead Sciences.

² Translator’s note: the point numbers here and in the next paragraph refer to Order No 3718-p.

of the Civil Code of the Russian Federation [and] the Constitution of the Russian Federation are based on an erroneous interpretation of the legal norms.

The Constitution of the Russian Federation, taking into account that the Russian Federation, as a democratic rule-of-law state shall ensure the recognition, observance and protection of human and civil rights and freedoms, the uniformity of the status of an individual throughout its territory, as well as the protection of other constitutional values, and presuming that the exercise of the rights and freedoms of the individual and citizen shall not violate the rights and freedoms of other people (part 3 of Art. 17), provides for the possibility of restricting rights and freedoms to the extent necessary for the protection of the foundations of the constitutional order, morality, health, the rights and lawful interests of other people, for ensuring defence of the country and security of the state (part 3 of Art. 55).

When determining the criteria for the admissibility of restrictions on constitutional rights and freedoms, the Constitutional Court of the Russian Federation indicated that the goals of such restrictions should be not only legally, but also socially justified, and the restrictions themselves should correspond to these goals and meet the requirements of justice; if it is permissible for a federal law to restrict one right or another in accordance with the constitutionally approved goals, only measures that are not excessive, but necessary and strictly conditioned on these goals should be applied; public interests listed in Art. 55 (part 3) of the Constitution of the Russian Federation can justify legal restrictions on rights and freedoms only if they are adequate to a socially necessary result; in the course of legal regulation, distortion of the very essence of constitutional rights or freedom is unacceptable, while the goals (tasks) of the rational organisation of the activities of the authorities alone cannot serve as a basis for restricting rights and freedoms (Resolutions of 22 June 2010 No. 14-II, of 13 July 2010 No. 16-II, etc.)

By virtue of Art. 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms, concluded in Rome on 4 November 1950, the restriction must be provided for by law and be necessary in a democratic society in the interests of national security and public order, the economic well-being of the country, to prevent disorder or crimes, for the protection of health and morals or the protection of the rights and freedoms of others. Article 6 of the Siracusa principles on the interpretation³ of limitations and derogations from the International Covenant on Civil and Political Rights (1985) (hereinafter “the Siracusa Principles”) states that no restrictions shall be applied for any purpose other than the one for which they were introduced.

In accordance with the provisions of the Civil Code of the Russian Federation, exclusive rights in the results of intellectual activity and means of individualisation established under international treaties of the Russian Federation and the Civil Code of the Russian Federation (point 1 of Art. 1231) are binding within the territory of the Russian Federation. Within the territory of the Russian Federation, exclusive rights in inventions, utility models and industrial designs certified by patents issued

³ Translator’s note: the official title of the Siracusa Principles is “Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights”; the Court’s reference to “the principles on the interpretation” can be understood as referring to Part I section A of the Siracusa Principles – “General Interpretative Principles Relating to the Justification of Limitations”.

by the federal executive body for intellectual property or by patents valid on the territory of the Russian Federation are recognised in accordance with international treaties of the Russian Federation (Art. 1346).

Persons who are not owners of exclusive rights to the results of intellectual activity (rightholders), as a general rule, may not use the results of intellectual activity without the consent of the rightholder (point 1 of Art. 1229 of the Civil Code of the Russian Federation). Meanwhile, as an exception, the Code establishes restrictions on exclusive rights to the results of intellectual activity, including in the case when the use of the results of intellectual activity is allowed without the consent of the rightholders, but with the preservation of their right to remuneration (point 5 of Art. 1229 of the Civil Code of the Russian Federation).

According to Art. 1360 of the Civil Code of the Russian Federation (as amended by Federal Law No. 107-Ø of 30 April 2021), the Government of the Russian Federation has the right, in case of emergency related to ensuring the defence and security of the state, and the protection of citizens’ life and health, to decide on utilising an invention, utility model or industrial design without the consent of the patent holder, notifying him of this as soon as possible and paying him proportionate compensation (point 1). The methodology for determining the amount of compensation and the procedure for its payment are to be approved by the Government of the Russian Federation (point 2).

The amendment by Federal Law No. 107-Ø of 30 April 2021 of Art. 1360 of the Civil Code of the Russian Federation by stating that it applies additionally for the purpose of protecting the life and health of citizens, in essence, did not change its previous semantic content.

The legislator, having made the corresponding amendments to the aforementioned norm, clarified the instances in which the Government of the Russian Federation has the right, in the interests of defence and security, to authorise the use of an invention, utility model or industrial design without the consent of the patent holder, without extending the list of grounds for taking a decision compared to those previously established.

The use of an invention, utility model, or industrial design in national security interests is an exception to the patent monopoly.

The restriction of exclusive rights enshrined in Art. 1360 of the Civil Code of the Russian Federation is not a case of free (without compensation) use of the patented subject matter. The issuance by the Government of the Russian Federation of permission to use the patented subject matter without the consent of the patent holder entails paying the latter a commensurate compensation.

Unlike compulsory licensing, which constitutes the conclusion of an agreement on a mandatory basis (Art. 1362 of the Civil Code of the Russian Federation), the use of the patented subject matter in the interests of national security is carried out on a non-contractual basis: permission to use the invention is not given by the patent holder (and the court does not compel the patent holder to give consent) and the State. At the same time, permission to use the subject matter of patent rights in the interests of national security is given without the consent of the patent holder, who is only notified of the given permission as soon as possible.

The lawfulness of a decision regarding the implementation of such a use of a patented subject matter can be challenged in court, as well as a decision regarding compensation paid in connection with the use of a patented subject matter, which creates certain protection of the rights of the patent holder.

The provisions of Art. 1360 of the Civil Code of the Russian Federation correspond to the provisions of Art. 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter “the TRIPS Agreement”) (concluded in Marrakesh on 15 April 1994) and are consistent with the Siracusa Principles.

The Siracusa Principles define that the aspiration to protect the health of the population can serve as a basis for limiting certain rights if the state needs to take measures to eliminate a serious threat to the health of the population or individuals. Such measures can be directed directly at preventing disease or a threat to physical health, or at providing care for the sick or injured. Due regard shall be given to the international standards of healthcare adopted by the World Health Organization (iv). National security refers to the protection of the existence of a nation or its territorial integrity or political independence against force or the threat of force (vi).

In carrying out the legal regulation of these relations, the federal legislator takes into account the provisions of international treaties to which the Russian Federation is a party, including the Convention for the Protection of Industrial Property, the Eurasian Patent Convention and the TRIPS Agreement.

The TRIPS Agreement, regulating the issues of recognition and protection of the main objects of intellectual property, in Art. 31 provides that the legislation of a member state can allow the use of patented subject matter without the permission of the rightholder in the event of an emergency or other circumstances of extreme necessity, subject to a number of conditions.

Provisions of Federal Laws of 28 December 2010 No. 390-ФЗ “On Security” and of 28 June 2014 No. 172-ФЗ “On Strategic Planning in the Russian Federation”, the National Security Strategy of the Russian Federation, approved by the Decree of the President of the Russian Federation of 31 December 2015 No. 683, the Strategy for the development of healthcare in the Russian Federation for the period up to 2025, approved by the Decree of the President of the Russian Federation No. 254 of 6 June 2019, envisage that national security includes the country’s defence as well as other types of security provided by the Constitution of the Russian Federation and the legislation of the Russian Federation, including personal security.

By virtue of para. 2 of Art. 2 of the Federal Law of 21 November 2011 No. 323-ФЗ “On the Basics of Health Protection of Citizens in the Russian Federation”, the protection of the health of citizens is a system of measures of political, economic, legal, social, scientific, medical, including sanitary and anti-epidemic (preventive) nature, carried out by the state authorities of the Russian Federation, state authorities of the constituent entities of the Russian Federation, local government bodies, organisations, their officials and other persons, [and] citizens to prevent diseases, preserve and strengthen the physical and mental health of every person, maintaining their long active life, providing them with medical care.

The said federal law refers to the basic principles of health protection as the observance of the rights of citizens in the field of health protection and the provision of state guarantees related to these rights, the responsibility of state authorities and

local governments, officials of organisations for ensuring the rights of citizens in the field of health protection (points 1 and 5 of Art. 4).

A public health emergency of international concern is defined by the International Health Regulations (2005) as an extraordinary event that: (i) constitutes a public health risk to other States through the international spread of disease, and (ii) might require coordinated international response measures. A public health risk means a likelihood of an event that may adversely affect the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger [paras. 55-57, 59, Art. 1(1)].

On 30 January 2020, the World Health Organization assigned the status of international danger to the epidemiological situation caused by the outbreak of the coronavirus infection and declared an emergency of international concern.

At the time of issuing the contested act, the Government of the Russian Federation had data that COVID-19 is characterised by a high level of contagiousness, a severe course of the disease, especially among patients of risk groups, and a high mortality rate.

In accordance with clause 72 of the National Security Strategy of the Russian Federation, sub-clauses 6 and 7 of clause 23 of the Strategy for the Development of Healthcare in the Russian Federation for the period up to 2025, threats to national security in the field of public health include the emergence of epidemics and pandemics; the risk that the epidemiological situation becomes complicated against the background of an unfavourable situation in foreign countries with regard to a number of new and dangerous infectious diseases; the risk of new infections caused by unknown pathogens; [and] the introduction of infectious and parasitic diseases that are rare or not previously encountered within the territory of the Russian Federation.

As follows from the content of the Order, the use by the Pharmasintez Joint Stock Company of inventions protected by Eurasian patents owned by the administrative claimants without the consent of the patent holders is allowed for a period of 1 year, subject to the payment of proportionate compensation to the patent holders. The scope and duration of the use of inventions are limited by the purpose specified by the Order, namely, providing the population of the Russian Federation with drugs with the international non-proprietary name “Remdesivir”, which follows from the text of the Order.

According to the legal position of the Constitutional Court of the Russian Federation, set out in the Decree of 25 December 2020 No. 49-II, the choice of legal means aimed at protecting the life and health of citizens in situations related to the spread of diseases, as a general rule, falls under the discretion of the legislator, and if such legal means have the character of measures restricting other rights, then it falls under the discretion of the federal legislator, as far as the Russian legal system is concerned. At the same time, the lack of legal regulation, adequate in its content and envisaged measures to an emergency situation threatening the life and health of citizens, despite the fact that such a threat is real and unconditional, cannot be an excuse for the inaction of public authorities to prevent and reduce cases of death and serious diseases. Such inaction would mean the elimination of the state from fulfilling its most important constitutional duty, which is to recognise, observe and

protect human and civil rights and freedoms, and, in fact, would lead to ignoring such duty due to a purely formal interpretation of the constitutional principle of the rule of law (Arts. 2 and 18 of the Constitution of the Russian Federation), without taking into account that the interests of protecting the life and health of citizens under certain circumstances may prevail over the value of preserving the usual legal regime for the exercise of other rights and freedoms.

The need to protect the life and health of citizens in the event of emergencies or the threat of their occurrence and the implementation of measures to combat epidemics and eliminate their consequences – taking into account the fact that human life is the highest constitutional value, without which the realisation of civil, economic, social and other rights becomes largely meaningless – involves the adoption of such legal acts that do not exclude the possibility of restricting human rights and freedoms, but only to the extent that this corresponds to the set goals, while observing the requirements of commensurability and proportionality.

Thus, in spite of the arguments of the administrative plaintiffs concerning the violation of their rights and freedoms, the Order was issued in connection with the current unfavourable epidemiological situation in foreign countries, characterised by the rapid spread of COVID-19, taking into account the official recognition by the World Health Organization of the spread of COVID-19 as an emergency in the area of public health, which is of international concern, to ensure the national security of the Russian Federation, part of which is the protection of human life and health.

A different assessment by the administrative plaintiff of the circumstances of the case related to the extreme necessity and interests of national security, which differs from the legal position of the administrative defendant, does not indicate the illegality and groundlessness of the contested Order adopted by the Government of the Russian Federation in specific conditions in accordance with the requirements of the law and a real threat to public health.

Contrary to the assertions of the administrative plaintiffs, the Order does not contradict the provisions of the Eurasian Patent Convention and the Convention for the Protection of Industrial Property.

By virtue of point 1 of Art. 1 of the Eurasian Patent Convention, the contracting states maintain complete sovereignty to develop their national systems for the protection of inventions. Compulsory licenses for the use of a Eurasian patent by third parties with effect within the territory of this state can be issued by the competent authority of a contracting state [established] in accordance with the Paris Convention for the Protection of Industrial Property (point 1 of Art. 12).

Based on the said provisions, within the framework of the Eurasian Patent Convention, compulsory licensing is also attributed to the competence of the contracting states.

In addition, the European Court of Human Rights held that health policy issues are, in principle, within the competence of national authorities, who are best placed to assess priorities, the use of resources and social needs. In this regard, the national authorities are primarily responsible for initially establishing and assessing a fair balance of the need for intervention into public interest with respect to the rights of individuals. Accordingly, in enacting legislation aimed at balancing competing interests, states should in principle be allowed to determine the means they deem

most appropriate to achieve the goal of those interests. Health policy issues are in principle within the purview of national authorities, who can best assess priorities, the use of resources and social needs. The margin of appreciation of the respondent state will usually be broad if a balance is to be struck between competing private and public interests or convention rights (see decision in *Hristozov and Others v Bulgaria*, Nos. 47039/11 and 358/12, para. 119, ECtHR 2012; decision in *Evans v the United Kingdom* [GC], No. 6339/05, para. 75, ECtHR 2007-I).

In turn, the Order does not restrict the circulation of the patented drug Vekluri and does not prevent the administrative plaintiffs from carrying out economic activities in the Russian Federation, including through the strategic partner – Pharmstandard Joint Stock Company.

Other arguments of the administrative plaintiffs related to disagreement with specific actions of the Federal Antimonopoly Service and the Ministry of Health of the Russian Federation, including the registration of the medicinal product and price setting, do not relate to the content of the Order and can be examined according to the standard procedure when the administrative plaintiff appeals against such decisions, actions (inaction).

Since the contested act, adopted by the authorised body of state power in accordance with the requirements of the legislation of the Russian Federation, does not contradict regulatory legal acts that have greater legal force,⁴ is exclusively temporary in nature, is aimed at providing the population of the Russian Federation with medicines, [and] does not violate the rights and lawful interests of the administrative plaintiffs in the aspects indicated by them, the administrative statement of claim is not held to satisfaction in accordance with point 2 of part 2 of Art. 227 of the Code of Administrative Judicial Procedure of the Russian Federation.

Based on Arts. 175–180, 227 of the Code of Administrative Judicial Procedure of the Russian Federation, the Supreme Court of the Russian Federation decided:

to refuse to satisfy the administrative statement of claim of Gilead Pharmasset LLC (US), Gilead Sciences Inc. (US) challenging the Order of the Government of the Russian Federation of 31 December 2020 No. 3718-p.

The decision can be appealed to the Board of Appeals of the Supreme Court of the Russian Federation within one month from the date of its adoption in final form.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

⁴ Translator's note: “greater legal force” corresponds to *большую юридическую силу* in the original. The word *большую* can be read as “greater” (if the first syllable is stressed) and as “great” (if the second syllable is stressed). From the context, it appears that “greater” (compared to the contested Order) is implied.