

# The Russian Supreme Court upholds the Order of the Russian Government on the compulsory licensing of Gilead's Covid-19 patents

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📖 INTELLECTUAL PROPERTY, RUSSIA

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**O**n 27 May 2021 the Supreme Court of the Russian Federation adjudged a legal action of US company Gilead seeking the cancellation of the order of the Russian Government no. 3718-p (the Order) issued on 31 December 2020. This order was the first example of enforcement of the power of the Russian Government to grant a compulsory license for the use of a patent in Russia without the consent of the patent holder based on article 1360 of the Russian Civil Code.

In a previous article (“Medicines for the therapy of the Covid-19 syndrome, political discretion and the bypassing of patent rights in Russia in an unprecedented legal scenario” at [https://www.lexology.com/library/detail.aspx?g=4616f1af-e652-47ad-8ff7-](https://www.lexology.com/library/detail.aspx?g=4616f1af-e652-47ad-8ff7-af39807c8b56)

[af39807c8b56](https://www.lexology.com/library/detail.aspx?g=4616f1af-e652-47ad-8ff7-af39807c8b56) ) we reported that the Order had allowed the Russian company Pharmasintez to use certain Gilead patents on non-exclusive basis till the end of 2021 against payment of adequate compensation to the patent owner. Earlier, Pharmasintez had failed to agree the license with Gilead and on that basis had asked the Russian Government to grant it a non-exclusive right to use the Eurasian patents of Gilead to produce and market in Russia its registered product Remdeform (based on the Gilead patented substance Remdesivir) as a medicine for the therapy of the Covid-19 syndrome.

In April 2021 Gilead filed a lawsuit with the Supreme Court of the Russian Federation (case no. AKPI21-303) challenging the Order and arguing that it divested the patent owner of the right to choose its licensees, to control the



quality and production volume of the product and the amount of the license consideration. Besides, Gilead claimed that the aims referred to in the Order did not correspond to those stated in article 1360 of the Civil Code, namely national defense or security. According to the text of the Order, the purpose of granting the license was to provide the Russian population with medicinal product Remdisivir, which is being used in the therapy of Covid-19.

At the same time, the Russian legislature enacted an amendment to article 1360 of the Civil Code (Federal law no. 107-FZ dated 30 April 2021) which is relevant to the subject. According to the new version of the text, the Russian Government may decide on the use of a patent without the consent of the holder also in cases of emergency connected with the State defense, Statesecurity and citizens' life and health. The Russian Government is obliged to notify the patent owner within the shortest possible time and to pay an adequate compensation. The compensation calculation method and the payment terms remain to be defined by the Government.

The Supreme Court rejected the claims of Gilead and upheld the Order granting the right to use the Gilead patents to Pharmasintez. The Supreme Court found neither formal nor substantive grounds for cancelling the Order, and adjudged that the claimant had incorrectly interpreted the law.

In its judgment, the Supreme Court referred to the Russian Constitution, the Russian Civil Code, the Convention for the protection of Human rights and Fundamental Freedoms signed in Rome in 1950 (ECHR), the Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights, 1985 (Siracusa Principles) and the Agreement on Trade-Related Aspects of Intellectual Property Rights, signed in Marrakesh, Morocco on 15 April 1994 (TRIPS Agreement) as a legal grounds.

The Supreme Court explained that, despite the fact that the goals of security of life and health of citizens as a ground

for granting of the use right was introduced in article 1360 only since 11 May 2021, the core-meaning of that article had not changed, as the amendment only elaborated the applicable cases, while the grounds for the grant were not broadened. The Supreme Court further clarified that the wording of article 1360 correspond with article 31 of the TRIPS Agreement and conform with the Siracusa Principles allowing limitations of rights for the purpose of protecting health, and in order to take measures for elimination of the health threats. Moreover, the TRIPS Agreement foresees cases of use of a patent without the consent of the rightholder in national emergency situations or other circumstances of extreme urgency.

The Supreme Court, in that way, created a link between the requirement of article 31 of the TRIPS Agreement, Russian legislation on State security, strategic planning, protection of the health of citizens and public health emergencies on the basis of the announcement of 30 January 2020 of the international emergency situation by the World Health Organization (WHO) in connection with the Covid-19 pandemic. The Order was considered by the Court to strike a proportioned balance with the rights of the patent owner for the purpose of protection of public health in Russia.

In addition, the Court also referred to the Eurasian Patent Convention as a proof of the competence of the Russian Federation over the Eurasian patent protection in its territory and cited two decisions of the European Court of Human Rights (case Hristozov and others v. Bulgaria applications nos. 47039/11 and 358/12, § 119, the European Court of Human Rights, 2012 (extracts) and case Evans v. United Kingdom no. 6339/05 §77, the European Court of Human Rights, 2007 I) as a confirmation of the wide discretion enjoyed by the Contracting Parties to the European Convention in balancing public and private rights and interests.

Finally, the Supreme Court held that the Order does not restrict the marketing of Gilead's medicinal product Velkuri or its

other commercial activities in Russia, including its existing partnership with Russian company JSC Pharmstandart.

The decision of the Supreme Court can be appealed at the Appeal Council of the Supreme Court of the Russian

Federation within a month; so in fact the term for filing an appeal claim already expired. At the moment, the case information page on the site of the Supreme Court does not contain any information about an appeal in this case.



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