

Newsletter

Expanding compulsory licensing into Life Sciences industry

May 17, 2021

Dear Ladies and Gentlemen,

We would like to inform you that the Russian President has signed amendments to Article 1360 the Civil Code of the Russian Federation ("**Russian Civil Code**"), in terms of providing compulsory licenses to use an invention, utility model or industrial design ("**patent rights**") on 30 April, 2021. The amendments came into force on 11 May, 2021.

These amendments allow the Russian Government to permit the use of patent rights, without the consent of the patent holder, by notifying him of this decision and paying proportional compensation, in case of emergency, related to ensuring national defense, state security, and/or protecting the life and the health of Russian citizens.

The methodology for determining the amount of compensation, and the procedure for its payment, shall be approved by the Russian Government.

Previous Compulsory Licensing Regulation

The Russian laws provided for granting a compulsory license, for objects of patent rights, only **in two cases**:

- by a judicial procedure;
- with the permission of the Government of the Russian Federation, in the interests of national security.

In the first case, in June 2018 the Moscow Commercial Court, for the first time, used a judicial procedure, of granting compulsory non-exclusive license to the Russian company Nativa for Lenalidomide, which is protected by the patent owned by the American corporation Celgene. The court acknowledged that the new medicine and new invention are dependent on another. It could not be used by the owner without violating the rights of the owner of the first patent holder, while the new invention had important technical achievement and significant economic advantages over Celgene's invention.

In the second case, on December 31, 2020, the Russian Government adopted the Order No. 3718-p ("**Order**"), which allowed the Russian company Pharmasintez to produce a medicine with an international non-proprietary name Remdesivir, a medicine for the therapy of COVID-19, during 2021, without the consent of Gilead Sciences, Inc., the holder of patent for this medicine.

Consequences of the adopting the new edition of Article 1360 of the Russian Civil Code

By adopting the new edition of Article 1360 of the Russian Civil Code, the powers the Government to apply compulsory licensing are expanded, namely, the article is supplemented by the right to make a decision on compulsory licensing, not only in the interests of the national defense and security, but also "*to protect the life and health of citizens*". At the same time the wording of the article was supplemented by the reservation that this right should be applied only "*in case of emergency*", which, in our opinion, does not limit the discretion of the Government.

The new edition of this article may stimulate the increase of compulsory licenses issued in the Life Sciences industry. Until the systematic practice of applying this rule has developed, it is rather difficult to give estimates and forecasts for its further application.

It is expected that the Russian Government shall adopt the methodology for determining the amount of compensation, and the procedure for royalty payments, for the issuance of a compulsory license.

At the moment this methodology does not exist, the draft of this document has not been designed and is therefore not in the public access.

We will continue to monitor developments in this area and will be ready to provide the necessary legal support on issues related to ensuring the interests of right holders in Russia.

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If you have any questions,
please, do not hesitate
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Sincerely,
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