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The new system of compensation for the compulsory licensing of pharmaceutical patents during health emergencies in Russia. Uncertainties and critical features

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On 31 December 2020, the Russian Government resorted for the first time to its statutory power pursuant to article 1360 of the Russian Civil Code, and ordered the grant of a patent license without the consent of the rightholder (please see details in our 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-af39807c8b56).

More particularly, article 1360 of the Russian Civil Code already allowed the grant of the right to use any patent for purposes of State defense and security (in other words, foreseeing instances of compulsory licensing under those circumstances). Government order no. 3718-p of 31 December 2020 rested on the COVID-19 pandemic as grounds for authorizing Russian company Pharmasintez to use 5 patents owned by Gilead Sciences, Inc. and produce patent protected medical products employed in the therapy of COVID-19.

The patent owner challenged the order by an action before the Supreme Court in April 2021.
Substantially at the same time, an amendment to article 1360 was enacted on 30 April 2021, which specifically allowed use of patents for inventions, utility models or industrial designs in

case of absolute necessity/emergency related to State defense and security, or protection of citizens' life and health.

In adjudging Gilead's action, the Supreme Court found that the new wording of article 1360 of the Civil Code was applicable, and by its decision no. AKPI21-303 dated 27 May 2021 held that the same amounted to sufficient grounds for the challenged order.

The Supreme Court furthermore held that part 3 of article 55 of the Constitution of the Russian Federation allowed restrictions of rights to the extent that the same are essential for the protection of the constitutionally established State order, morality, health, rights of others, defense and security of the State. Thus, it concluded that the Gilead order had been adopted in line with the main principles of the Russian law.

In support of its judgement, the Supreme Court cited article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950 (ECHR), and article 31 of the TRIPS Agreement of 1994, which consider health protection sufficient grounds for restrictions to rights in general, including intellectual property rights. The Court held that the amendment to the text of article 1360 of the Civil Code had not changed its core meaning, and merely specified the applicable cases, without affecting the grounds.

Further, the Supreme Court observed that the Government order had granted Pharmasintez the right to use the Gilead patents for a limited period of time of 1 year, had prescribed the payment of compensation for such use, and had not restrained the grant of licenses to other companies or other uses of the Gilead patents by the rightholder in Russia.

To sum up, the Supreme Court rejected Gilead's claims, and its judgement, arguably for reasons of political convenience, was not appealed by Gilead.

Earlier this year, the Russian press reported that Pharmasintez as the user (i.e. compulsory licensee) of the Gilead patents had opened a letter of credit in the name of the patent owner for the amount of $ 66 349.51 US valid till 22 March 2022. The amount does not strike one as being shattering.

The recent amendment to article 1360 of the Civil Code also empowered the Russian Government to define the criteria of calculation of the rightholder's compensation and the payment methods. On that basis, the Government issued a specific regulation on the calculation of compensation and its payment (Resolution of the Russian Government no. 1767 dated 18 October 2021). The regulation came into effect on 28 October 2021.

In accordance with item 2 of the Resolution, compensation shall be calculated at the rate of 0,5 (zero point five) per cent of the actual operating income derived from the production and sale of the protected goods and services, where the relevant invention, utility model or industrial design has been used without the rightholder's consent.

The compensation shall be calculated on a yearly basis for the period of grant of the right of use and shall be paid by each entity having exercised the granted right.

The Resolution furthermore specifies that in cases where the production of the relevant goods requires the use of several patents, the compensation shall be calculated on the basis of general rule, but shall be split into parts between relevant patent holders in proportion to the number of patents used. As a result, it does not matter how many patents are used, and the amount of the compensation shall only depend only on the actual revenue obtained from the goods produced or services provided through the use of the patent or patents. Significantly, the Resolution does not require any correlation between compensation and fair market value of the license.

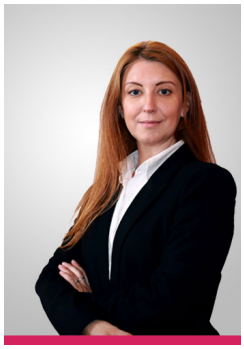
Looking at the fair market average royalty rates that apply worldwide to voluntary licenses under pharmaceutical patents for new, groundbreaking active

substances and antibodies, and even considering the general interest element that naturally underlies a compulsory license on grounds of a public health emergency, one cannot help to note that a 0.5 percent rate applied on the entire patent pool that may be relevant, appears at first sight to lack proportionality and liken for practical purposes a nominal compulsory license to a de facto, quasi-expropriation of property without the guarantees and legal protections foreseen by the ECHR and the TRIPS Agreement. On the other hand, one could argue that, in the absence of definitions in Article 31 of the TRIPS Agreement of terms “adequate remuneration” and “economic value of the authorization”, the Russian Federation may enjoy a full freedom of evaluation.

As concerns payment of the compensation, the Resolution foresees two options available to the user-licensee. Once the compensation amount is calculated for the year of the patent use, the entity may credit the relevant sum to an irrevocable letter of credit opened to the benefit of the patent owner and inform the same thereof, or offer to the rightholder to conclude a specific agreement on the payment of the applicable compensation laying down the applicable terms and conditions. The relevant actions according to such option must be put in place within 30 consecutive days from the year end, and payment of the compensation must be made within 6 months from the date of signing by the patent owner of the agreement offered by the user-licensee.

The Resolution does not provide further details, namely, on the procedure for negotiating the terms and conditions of the agreement for payment of the compensation, and objectively place the user-licensee in a disproportionately stronger position. The only certainty is that there is a legal obligation to pay compensation, but the modalities and ultimately timeframe of payment for practical purposes remain within the discretion of the Russian user-licensee.

It is finally noted that, if the new governance of compulsory licensing of IP rights on grounds of public health emergencies in Russia that results from the amended text of article 1360 of the Civil Code coupled with Resolution no. 1767 of 18 October 2021 supplies a minimum of certainty as to the right to compensation of the proprietor of the relevant patent(s), there is no certainty as to the mode and time of its payment instead. But of much greater concern upstream of that, is a system that seems to open the door to a quasi-expropriation in disguise of highly valuable and sensitive patents, very often owned by foreign rightholders. One may wonder if that is a forward-looking course to build on, in order to achieve an environment of self-supporting R&D within the domestic Russian pharma industry.



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