Medicines for the therapy of the Covid-19 syndrome, political discretion and the bypassing of patent rights in Russia in an unprecedented legal scenario

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Article 1360 of the Civil Code of the Russian Federation (the Civil Code) provides for a derogation from the exclusive right of the patent proprietor to exploit its invention, utility model or industrial design, if the Government grants that right to a third party without its consent. This can be done on grounds of national defense and security and is subject to prior notice to the rightholder and payment of adequate compensation. The law does not explain what the adequate compensation is and how it should be calculated. The text of article 1362 states that the court shall determine the amount of the compensation, but article 1360 does not equally refer to the court competence and for practical purposes leaves the issue of adequate compensation to the Government discretion's.

This power was never used since the adoption of the Civil Code in 2006, and it is unclear whether it should be assimilated to a particular form of expropriation in the public interest, or rather a particular form of compulsory licensing.

The subject is bound to become the object of discussion, since, in early 2021 the Russian press unexpectedly revealed that the Russian Government issued order no. 3718-p of 31 December 2020

(the Order) exercising that power for the first time.
The Order expressly refers to article 1360 of the Civil Code and grants the right of non-exclusive use of 5 Eurasian patents belonging to Gilead Sciences, Inc. all in force in Russia, and one Eurasian patent belonging to Gilead Pharmasset LLC likewise in force in Russia, to the Russian company Pharmasintez. The Order states that the purpose of granting that right to use the Gilead patents is to provide the Russian population with medicinal product Remdisivir, which is an anti-retroviral active principle that is being used in the therapy of the Covid-19 syndrome.

The Russian press furthermore reported that Pharmasintez had previously registered medicinal product Remdeform based on Remdisivir, and in November 2020 subitted to the Russian Government an official undertaking to produce Remdeform in a quantity of 1,2 mln. vials during the first half of 2021. The patent holder, Gilead, also registered a medicinal product based on Remdisivir in Russia, named Vekluri. Both Pharmasintez's and Gilead's registrations are valid till 2022.

Pharmasintez claims to have turned to Gilead in July 2020 asking for a voluntary patent license, and that their request remained unanswered.

In accordance with the Order, Pharmasintez has the right to use the Gilead patents for a one year period and is obliged to pay adequate compensation to the proprietor within 3 months. The Ministry of Health of the Russian Federation must notify the holders of the patents of the use authorized by the Order before the expiry of a 30 day period after the first sale of the medicinal product containing Remdisivir.

It should be noted that article 1362 of the Civil Code provides for the possibility to obtain the non-exclusive right to use a patent based on a compulsory license. The compulsory license may be granted by a court decision (not an administrative order), on the cumulative condition that (a) the patent was not used for 4 years after the date of grant, (b) the patent-holder refused to conclude a license agreement with a willing potential licensee, and (c) there is a lack of supply of goods on the market for the patent-based products. The license based on article 1362 should be claimed by lawsuit. In accordance with the general rule of the Arbitrazh Procedure Code (article 65) each party shall prove the circumstances its claim relies on. This means that the party claiming the right to use the patent will be expected to prove in court that there is need for and lack of the relevant goods protected by the patent on the market. The court assesses the evidence supplied and adjudges the claim on that basis.

Therefore, Pharmasintez might have obtained an ordinary compulsory license from Gilead by filing an action in the Russian courts. However, the time criterion set by law for compulsory licensing is currently met only for 3, out of the 6 Eurasian Gilead patents relative to Remdisivir, and the prescribed 4 years period for all 6 patents will expire only in 2023, which made the compulsory license option unviable before that time.

This may be the reason why Pharmasintez chose to apply for an order under article 1360 of the Civil Code, rather than for a compulsory license under article 1362.

However, it looks unclear how Remdesivir-based medicinal products relate to and could benefit the defense and security interests of Russia. The Russian Government has not given reasons or provided explanations in the Order. Whilst neither the text of article 1360 of the Civil Code, nor other Russian laws contain a specific definition of defense and security, there is no doubt that the Government is competent and enjoys political discretion to take measures that ensure the defense of the country and the security of the State (article 24 of the Federal Constitutional Law "About the Government of the Russian Federation" no. 4-FKZ dated 06 November 2020).

On the strength of the Order, Pharmasintez has obtained the right to produce and market in Russia its

registered product Remdeform during the whole of year 2021. The adequate compensation payable to Gilead remains undetermined and, in any event, undisclosed. At the same time, the Order does not restrict or affect the right of the patent-holder to sell in Russia its registered product Vekluri. The current situation seems to pave the way for competition between two Remdisivir-based products and producers, which is contrary to the principle of exclusivity of the patent right as a compensation for the disclosure of the invention, and in itself disrupts the balancing of interests which is one of the pillars of intellectual property at large, amongst others, as enshrined in the 1994 TRIPS Agreement, which is an international treaty that binds Russia and is a constituent part of its legal system.

Finally, it should be borne in mind that the Order is a non-regulatory act, which could in the abstract be challenged before the Supreme Court of the Russian Federation in accordance with article 21 of the Code of Administrative Judicial Procedure.

To sum up, the legal scenario could not be more uncertain.

If the resort to the power foreseen by article 1360 of the Civil Code is in the substance a power of expropriation in the public interest, the formal requisites and legal guarantees for such a measure may well not be fulfilled. On the other hand, the Order itself could be likened to a political act exempted from judicial scrutiny in its merits. One might speculate that the use of the article 1360 special tool was a way to bypass the four-year non-exploitation requirement for there to be a proper compulsory license under article 1362. It remains to be seen if Gilead will challenge the Order, by judicial or diplomatic means with highly uncertain chances, and risk facing an adverse image and reputational fallout for resisting the broader use of a medicine that is useful to combat the Covid-19 pandemic and save human lives, or it will rather go for a Realpolitik solution, choose to co-exist (i.e. split the market) with Pharmasintez, negotiate an acceptable adequate compensation, shut its eyes on legal certainty and eventually benefit from the very important Russian market for Covid-19 anti-retroviral therapies.

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