Russian Government issues new export waiver for pharma patent, admittedly relying on Article 31 bis of the TRIPS Agreement

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Alisa Pestryakova

By an Order of December 2020 the Russian Government exercised for the first time the right to use patents without consent of the rightholder provided by article 1360 of the Russian Civil Code and article 31 of the 1994 TRIPS Agreement. On that legal basis, the Government granted a 1-year license for 5 patents belonging to US Gilead valid in Russia to a Russian pharma producer.

The Russian Government justified that measure on grounds of the COVID-19 pandemic and the need of medicines aimed at its prevention or therapy in a situation of lack of supply by the patent owner. Efforts and attempts of the US company to challenge the Government's Order in all instances, including the Supreme Court, failed.
At the same time, when the dispute was still being adjudged, the text of article 1360 of the Civil Code was amended, and life and health protection were added as grounds for the use of a patent without the consent of the right-holder. The initial wording referred only to defense and security needs as grounds for granting the right to use an invention, a utility model or an industrial design. On 18 October 2021, the Government issued Order no. 1767 laying down the method of calculation of the compensation owed to the right-holder.

By new Order no. 947 dated 25 May 2022 (Order) the Government re-formulated the legal basis for that measure with reference to article 31bis of the TRIPS Agreement. Article 31 bis had been introduced by the WTO in the Doha Declaration on the TRIPS Agreement and Public Health, and was adopted by the General Council's decision of 06 December 2005 as an amendment to the TRIPS Agreement. It provides for the permissibility of *"…a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible*

importing Member(s)…". The Order refers to the same article 1360 of the Civil Code previously mentioned, and approves the implementing Rules for the adoption of decisions on the use of patents without the right-holder's consent for purposes of production of pharmaceutical products for export purposes (Rules).

The Rules provide that the decision may be taken on the ground of certain listed requirements, to be cumulatively applied. The literal wording does not expressly say that the issuance of the decision is "subject to" the fulfillment of the relevant requirements, but use language "in conjunction" instead. In that context, this should be construed as prescribing compliance with all listed requirements.

Thus, one can say that the grant of a license for production of a pharmaceutical product without the right-holder's consent according to the Order, is conditional upon the following being met:

- Existence of a relevant notification from an eligible importing Member of World Trade Organization (WTO) to the Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS) of its intention to resort to the option provided for by article 31 bis of the TRIPS Agreement on terms set out in items 2 and 4 of the Annex to TRIPS Agreement. Item 2 provides that the importing Member shall include in its notification the name of the medicinal product, the expected quantities to be imported, a confirmation of the insufficiency of the product and its production, and information about the intended conditions for granting a compulsory license for production of the relevant product in its territory. Item 4 imposes a responsibility on the importing Member for ensuring the *"availability of effective legal means to prevent the importation into, and sale in, their territories of products"*;
- Existence of a relevant inquiry from an importing WTO Member on the possibility of production and supply of the medicinal product specifying quantity, delivery terms and purchase price;
- Existence of production capability to meet the requested quantity, quality, supply terms and price;
- Compliance with part (b) of article 31 of the TRIPS Agreement (specifying that efforts were made to obtain the consent of the right-holder on reasonable commercial terms and conditions, which proved unsuccessful);
- Conclusion of an agreement between the importing WTO Member and the producer(s) of the medicinal products.

The Order furthermore adopts the procedural provisions for the taking and termination of the licensing decision without the right-holder's consent and royalty calculation and payment method. The right-holder may expect receiving a royalty of 0.5% of the sale price of the product multiplied by the contractual quantity, which should be paid by a single payment. The same royalty rate is applicable to cases where several patents are used for production of the medicine or the relevant patent rights are owned by several holders, so the total sum is in that case split between all patents and/or right-holders.

The compensation must be paid by the seller of the pharmaceutical products within 30 days from receipt of payment therefor, by an irrevocable confirmed letter of credit opened with a major Russian bank, to be valid for 3 years. Alternatively, the producer may agree on ad hoc agreement on payment of compensation. The refusal of the right-holder to sign an agreement or its failure to claim payment under the letter of credit within 3 years terminates the payment obligation of the licensee.
The new Rules are in the wake of the earlier Order no. 1767 previously mentioned. The royalty rate was the same and amounted to 0.5% of the profit realized by the licensee, to be paid on a yearly basis during the term of the compulsory license.

It should be also noted that on 06 March 2022 the Russian Government added to the text of Order no. 1767 a specific provision, which seems connected to the current geopolitical situation. The amendment provides that the

compensation rate for the use of IP rights without the consent of foreign right-holders from so-called unfriendly States (48 countries, including all EU Members) shall be zero per cent.

The timing of Order no. 947 is very close to the recent WTO 12 Ministerial Conference that took place on 12-17 June 2022. On that occasion, a Decision was adopted referring to the exceptional circumstances of the COVID-19 pandemic and allowing the WTO Members to authorize *"… the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right-holder to the extent necessary to address the COVID-19 pandemic …"*. The WTO Decision is narrowly phrased and covers only ingredients and processes necessary for the manufacture of the COVID-19 vaccines, aiming to ensure availability of and access to the same. By contrast, Order no. 947 of the Russian Government does not include any reference or restrictions to specified pharmaceutical products falling under the new rules.

It is unclear if the new provisions were adopted as an implementing measure of the earlier provisions of article 1360 of the Civil Code, as a preparatory work for the WTO Conference, or there are real expectations of the Russian Government of requests from WTO Members for production of pharmaceutical products in Russia for export purposes, and if at a next stage foreign right-holders from unfriendly States will be also deprived of compensation for use of their pharmaceutical patents for export production.

Time will tell, but it is submitted that the net effect of Order no. 947 and the general export waiver introduced thereby may push the result beyond the letter and purpose of Article 31 bis of the TRIPS Agreement, even after the WTO Ministerial Decisions of June 2022.

Alisa Pestryakova

ASSOCIATE

a.pestryakova@dejalex.com

+7 495 792 54 92

Ulitsa Bolshaya Ordynka 37/4
119017 – Moscow

MILANO
Via San Paolo, 7 · 20121 Milano, Italia
T. +39 02 72554.1 · F. +39 02 72554.400
milan@dejalex.com

ROMA
Via Vincenzo Bellini, 24 · 00198 Roma, Italia
T. +39 06 809154.1 · F. +39 06 809154.44
rome@dejalex.com

BRUXELLES
Chaussée de La Hulpe 187 · 1170 Bruxelles, Belgique
T. +32 (0)26455670 · F. +32 (0)27420138
brussels@dejalex.com

MOSCOW
Ulitsa Bolshaya Ordynka 37/4 · 119017, Moscow, Russia
T. +7 495 792 54 92 · F. +7 495 792 54 93
moscow@dejalex.com