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Recent case law in Russia on patent term extension for last generation medicines

02/07/2020 INTELLECTUAL PROPERTY, RUSSIA

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Similarly to Regulation (EC) No 469/2009 on supplementary protection certificates for medicines Article 1362 of the Russian Civil Code provides the possibility of obtaining a patent term extension for medicinal products, as a compensation for the reduced duration of the effective term and patent monopoly owing to the need of medical trials and regulatory accomplishments for obtaining the marketing authorisation ("MA") required to place the medicine on the market. According to Article 1363 of the Civil Code, the extension may last to 5 years, provided the MA is issued more than 5 years after the original patent application date.

1. The ultimate aim under both the European Regulation and Russian law is the same, i.e. to supply a minimum effective protection of 15 years, which is considered an adequate span of time for the patentee to recuperate its R&D investments. However, there are certain significant differences with respect to both procedure and technical patent law features.

2. The Rospatent does not technically grant the extension by prolonging the term of the initial patent, but issues a new patent, which is valid for the extended period. The requirements and procedures for obtaining the term extension of a patent granted in Russia are laid down in the Administrative Regulation adopted by the Russian Ministry of Economic Development by Order no. 810 dated 03 November 2015 ("the Administrative Regulation") and the Procedure of issuance of additional patent and extension of patent term adopted by the Russian Ministry of Economic Development by Order no. 809 dated 03 November 2015 ("the Procedure").

3. Pursuant to the Administrative Regulation, the patentee seeking a term extension should provide together with the application and other listed documents, an existing or amended patent claim, which defines the same features as those specifically ascribed to the medicinal product in accordance with its granted MA. In part 1 of Article 8, the Procedure furthermore provides for certain distinctions:
a) for a chemical combination or group of chemical entities written in a patent claim as a chemical structure, the chemical combination claim should correspond to the active ingredient structure of the medicinal product according to its MA, and the description should both disclose the use of the chemical entity as an active ingredient and demonstrate the activity of the combination that enables its usage in the medicinal product according to the MA
b) for a composition or group of compositions written in a claim, the characteristics of the combination should correspond to the features of the active ingredient of the medicinal product under the MA.

4. There is little case-law on the subject. However, the Russian Court for Intellectual Property ("IP Court") recently adjudged two disputes on patent term extension for chemical substances used in pharmaceutical products that are worth reporting.

5. Pharmaceutical company Gilead Pharmasset LLS had filed with the Russian Patent Office ("Rospatent") an application for extension of its patent no. 2651892 on 20 August 2018. The patent covered as a substance isopropyl propionic acid or its stereoisomer, as an antiviral composition for treatment of hepatitis C with an effective amount of substance, and the method for producing it or its stereoisomer.
In its patent term extension application, Gilead had narrowed its initial claims down to one substance - sofosbuvir, a S-stereoisomer of the composition, which is the active ingredient of the pharmaceutical product under the relevant MA.
The Rospatent rejected the application. In the preliminary refusal decision it stated that substance sofosbuvir, referred to in both the MA and the application for term extension, was a specific stereoisomer of the molecular species claimed in the patent, and was not identical to the composition of the patent claim. In its final decision the Rospatent additionally stated that the S-stereoisomer claimed for extended protection, was not proved to be produced and was disclaimed in the patent description as an active ingredient useful for the claimed purpose, as prescribed under the Procedure.
Gilead challenged the Rospatent rejection before the IP Court in October 2018 (case SIP-740/2018, decision issued on 28 November 2019). The IP Court held that the Rospatent's refusal was inconsistent with the applicable legal provisions and annulled the decision.
The IP Court reviewed the patent claims and held that the basic patent no. 2651892 covered any stereoisomer of the chemical combination, including both S- and R-stereoisomers as alternatives. Each alternative had a separate set of features and should be compared with the medicinal product active ingredient structure separately, which the Court found had not been done by the Rospatent.
The second ground for refusal relied on by the Rospatent was the non-disclosure of sofosbuvir in the description of the invention as the specific substance in fact produced and possessed of the activity that was essential for the claimed purpose. The IP Court acknowledged that the stereoisomer was mentioned in the claim without showing the chemical structure or specific features, however, it considered that the description in general of the method to produce the chemical combination by the separation of the diastereoisomers was sufficient. Further, the IP Court held that the separation of diastereoisomers was the standard action in the field according to the state of the art, with the obvious effect of maintaining their features and activity, and the description of the general method without specific examples was enough to meet the requirement of the Procedure.
In its statement of defence, the Rospatent had moreover argued that the patent holder had deleted the S-

stereoisomer from patent claim no. 8), but the IP Court rejected that reasoning too, and confirmed that the composition utilizing the S-stereoisomer was still comprised within the main independent claim.
As a result, the IP Court annulled the rejection decision and directed the Rospatent to grant the patent extending the term of protection for the sofosbuvir substance under the MA for medicinal product Sovaldi.
However, the Rospatent disagreed with the decision of the IP Court, withheld the grant of the extension, and challenged the IP Court's decision in the cassation instance. The Presidium of the IP Court rejected the cassation appeal, and upheld the first instance judgment. The Presidium of the IP Court did not find any error of law or procedure at first instance proceeding, whilst assessments of fact remained outside the scope of the cassation instance.

6. In a different case, Genentech Inc. had filed an application for term extension of its patent no. 2326127 in 2018. The Rospatent issued a preliminary refusal of the application. The applicant filed its answer and arguments and amended the patent claim, but the Rospatent was not satisfied and eventually rejected the application.
Genentech challenged the rejection before the IP Court on 24 May 2019 (case SIP-417/2019, decision on 04 February 2020) arguing that the Rospatent, instead of assessing the requirements for term extension, namely, the correspondence of the amended claim to the features of the active ingredient of medicinal product Ocrevus (ocrelizumab), had examined the amended claim for the purposes industrial applicability.
Genentech furthermore criticized the Rospatent's decision for not directing an additional inquiry allowing the applicant to provide further data and information or further amend the patent claim, as well as failing to grant the term extension for claim no. 2, which had not been at the source of objections.
In support of its decision, the Rospatent explained that the patent claim in the term extension application had not included the relevant amino-acid sequence or antibody isotype of the antibody constant region, which was one of the characteristics of the active ingredient of product Ocrevus, namely, the isotype immunoglobulin G (IgG). In the absence of narrowing down the antibody isotype, the claimed group of antibodies was supposed to include all types of the antibody constant region.
The IP Court held that in order to assess the compliance with the requirements of part 1 of Article 8 of the Procedure, the Rospatent should answer the following questions:
(1)Does the patent claim describe the active ingredient of the medicinal product under the MA?
(2)Does the patent claim describe a combination or group of combinations with a single chemical structure?
(3)Does the patent description disclose that the chemical composition or group of compositions covered by the patent claim may be used as the active ingredient of the medicinal product?
(4)Does the set of features of the product protected by the patent claim correspond to the active ingredient of the medicinal product under the MA?
(5)Does the patent description plausibly disclose that the composition or group of compositions with a single chemical structure under the patent claim present the necessary activity for use in the medicinal product under the MA?
(6)Does the set of features of the composition under the patent claim correspond to the set of features of the composition of the medicinal product under the MA?
In assessing the relationship between the amended patent claims filed by Genentech for the term extension and the features of the active ingredient of the medicinal product under the MA, the IP Court requested written expert opinions and brought experts to the hearing to answer its own questions and those of the parties.
The summary of product characteristics stated that the treatment of multiple sclerosis indicated for medicinal product Ocrevus was based on certain effector functions of antibodies (antibody dependent cellular phagocytosis, antibody dependent cellular cytotoxocity, complement dependent cytotoxocity and apoptosis). These effector functions were

generally attributed to antibody isotype immunoglobulin G1 (IgG1) and moreover to immunoglobulins G2 (IgG2), G3 (IgG3), G4 (IgG4). Other antibody isotypes of the antibody constant regions, like IgA, IgD, IgE, IgM, should be either disclosed in the patent as having the same effector functions, or be obvious from the state of art.
During the proceedings, Genentech argued that one of the amended patent claims referred to the multiple sclerosis treatment as an indication of the composition, so that only substances with antibody isotypes immunoglobulins G of the group in claim no. 1) were supposed to be protected, despite the broad wording and without the need to disclose in the patent description proof of the accomplishing that function for other types of immunoglobulins.
Both experts confirmed that the active ingredient of Ocrevus was not identical to that in claim no. 1) in the application for term extension, as the composition characteristics did not include the amino-acid sequence or antibody isotype of the antibody constant region, so that the claim included a group of compositions of antibodies of all isotypes, while the Ocrevus active ingredient (ocrelizumab) referred to antibody isotype immunoglobulin G1 (IgG1). They further explained that the antibody effector functions, which made the treatment of multiple sclerosis possible, pertained mostly to immunoglobulins G1 and G3; however, the same functions characterize, besides IgG isotypes, also certain immunoglobulins M.
Further answering the questions posed by the Court concerning amended claim no. 2), the experts agreed that the composition there was identical to the active ingredient of Ocrevus, as the sequences listed in the claim were chains of immunoglobulin G1.
Based on the evidence given by the experts, the IP Court held that patent claim no. 1) was not identical to, and broader than, the composition of the active ingredient of the medicinal product under the MA. Namely, the claim was broader than ocrelizumab, since its wording included all isotypes of immunoglobulins without any proof of the treatment of multiple sclerosis for part of the antibody isotypes (immunoglobulins) disclosed in the patent description.
With regard to claim no. 2) and the argument of Genentech that the Rospatent should have granted the term extension therefor, the IP Court held that it had no obligation to grant a patent for that claim, as the applicant had applied for the term extension for all patent claims submitted and had not expressed its consent to any other decision of the Rospatent possibly granting the extension for certain claims only.
This decision was further challenged by Genentech in cassation instance, and the hearing was scheduled for 01 June 2020. Meanwhile, Genentech made an attempt to settle the dispute, and informed the Court about the ongoing correspondence on the matter with the Rospatent at that hearing. The IP Court postponed the hearing till 06 July 2020, satisfying the request of Genentech and encouraging the parties to find an amicable solution. If the parties fail to reach a settlement, the case may be finally determined by the IP Court Presidium on 06 July 2020.

7. These cases illustrate how the provisions of the Civil Code, the Administrative Regulation and the Procedure are applied in practice
Besides the general requirement that a patent term extension is possible only if the MA is issued more than 5 years after the original patent application date, the Administrative Regulation and the Procedure provide additional requirements:
i.the patent claim should be identical in structure or characteristics to the active ingredient of the medicinal product under the MA;
ii.the granted patent should disclose the use of the chemical composition and prove that its activity corresponds to that of the active ingredient under the MA.
The IP Court reviewed the identity of the patent claim and the active ingredient under the MA in both cases.
With regard to requirement i., the Court in fact compared the initial patent claim in the patent granted and that of the extension application with the composition of the active ingredient.
In the first case, the assessed active ingredient was found covered by the initial patent claim, and the patent claim

in the application exactly corresponded, i.e. was identical, to the chemical combination of the active ingredient of the medicinal product under the MA. The Court held that the relevant requirement was thus met. In the second case, the patent claim for the chemical composition as well was found to cover the entity of the active ingredient. However, the claim in the application included not only the composition of the active ingredient but also other chemical entities. It was thus broader than the chemical entity of the active ingredient, and the Court found that the identity criterion was not met. This could have been avoided by the applicant by utilizing a more precise wording, limiting the application claim to the active ingredient composition under the MA.

In order to assess compliance with requirement ii., the IP Court verified if the description of the initial granted patent disclaimed the use and confirmed characteristics of the specific chemical composition claimed for term protection extension, and such disclaimed possibility to use the composition and disclaimed functions were the same as those of the active ingredient of the medicinal product under the MA. The description should have confirmedthat the patent holder had disclaimed in the initial patent the use and efficiency of the active ingredient of the product under the MA.

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