ADVANT Beiten

Legal digest

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Healthcare

Русская версия

We present you with a digest of major legal news for May 2025 in the pharmaceuticals and medical products sector in Russia.

I. MEDICAL PRODUCT

1. Fighting counterfeit medical products

On 23 May 2025 the Thirteenth Commercial Court of Appeal (the "**Court**") upheld the decision of the Commercial Court of Kaliningrad Region in the case of the Japanese diagnostic equipment manufacturer *Sysmex Corporation vs Individual Entrepreneur A.I. Melnikov* [1], in which the lower court:

- declared the medical products supplied by Individual Entrepreneur A.I. Melnikov to Kirov Regional Clinical Hospital (the "**Hospital**") to be counterfeit;

- prohibited Individual Entrepreneur A.I. Melnikov from using the trademarks SYSMEX and CELLPACK regarding the supplied goods;

- compelled Individual Entrepreneur A.I. Melnikov to withdraw the contested goods from circulation and to destroy them.

Key facts of the case

- The Hospital requested that Individual Entrepreneur A.I. Melnikov present documents to confirm the actual introduction of supplied goods of foreign origin into civil circulation in Russia by the rights holder or with its consent (licence agreements of the supplier with the rights holder, customs declarations, contract with the licensee).

- In the end the Hospital refused the goods on the grounds that they were at variance with the requirements of the contract, as "*the goods are not free of third party rights of claim"*, in other words, Individual Entrepreneur A.I. Melnikov failed to prove that the exclusive rights to the trademark had been exhausted.

Important conclusions of the Court

- Individual Entrepreneur A.I. Melnikov failed to disclose the entire chain "*of the entry of the goods into the Russian Federation, and evidence confirming the source of origin and due quality of the goods*";

- "*The declarations for the goods submitted by the respondent to the court merely confirm the actual import of certain goods by the importer into the Russian Federation. The declarations do not contain information on the numbers of the consignments of such goods and do not confirm the source of origin of the goods*."

- The marking of the supplied medical products "*is at variance with the original marking that is inserted by the manufacturer and does not comply with the General Requirements on the Safety and Effectiveness of Medical Products, the Requirements on their Marking and the Operating Instructions for Them, approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated 12 February 2016*."

- "*A claim on declaring actions to be illegal/goods to be counterfeit is a type of declaration claim*".

The Court's judgment entered into force as of the date of its adoption and accordingly is enforceable. At the same time, however, Individual

Entrepreneur A.I. Melnikov filed a cassation appeal with the Intellectual Property Court which scheduled a court hearing for 9 July 2025.[2]

2. State procurements: review of cassation judgments

Cassation courts have considered a number of cases where state clients established requirements on the equipment to be procured in such a way that certain participants of state procurements held that they were restricting competition.

In such instances the participants of the procurements filed respective appeals with the antitrust authority which were in the end appealed in court.

Based on the analysed judicial practice, the courts sided with the state client in May.

We present below the important conclusions of the cassation courts regarding the correctness of the description of the subject matter of the procurement:

- **Requirements on the specifications of goods which attest *de facto* to a competitive model**

"the establishment of […] more stringent requirements on the equipment being procured was dictated by the innovation principle, which requires that the client use in its work hi-tech equipment that will make it possible to conduct trials at a higher professional level, which will have a direct impact on the quality of the medical assistance that they provide." [3]

"*the client takes into account the need to adopt the maximum possible measures to protect healthcare professionals […] during a medical procedure, the requirements included in the description of the subject matter of the procurement are attributable objectively to the client's needs […]*." [4]

"*the reference by the client in the auction documentation to particular features of the product which meet its requirements and are needed, taking into account the specifics of the use of such product, may not be considered a restriction on the range of potential participants of the procurement. […] the characteristics […] declared by […] constitute an objective requirement attributable to the specifics of their operations, the need for the professional provision of medical services, as well as compatibility with the equipment available at the institution […]*." [5]

- **The requirement that the equipment manufacturer confirm the compatibility of the consumables to be supplied**

The medical product (nucleic acid dosage and extraction complex) was being leased by the state client. The lease agreement stipulated the

obligation *"To use only those consumables whose compatibility with this equipment is confirmed by the supporting documentation of the equipment manufacturer."* In the event of the supply of goods, the state client verified the existence of such documents authenticated by the equipment manufacturer.

Position of the cassation court:

"*A reference in the description of the subject matter of the procurement to product requirements […] regarding the existence of confirmation from the equipment manufacturer of such compatibility is the right of the client to elaborate in detail the subject matter of the procurement, meets the client's requirements on the product's specifications, ensures the safe use of the original equipment, the correctness of the laboratory diagnostics being conducted, as well as the safety of the lives and health of healthcare professionals who are implementing laboratory diagnostics*." [6]

II. PHARMACEUTICALS AND NUTRITIONAL SUPPLEMENTS

1. Amendments to legislation

1.1 Law on regulating the circulation of nutritional supplements (Supplements)

The Federal Assembly of the Russian Federation approved and adopted in May - early June 2025 draft Law No. 638771-8[7], which introduces amendments to a number of Federal Laws, No. 29-FZ "On the Quality and Safety of Food Products", No. 149-FZ "On the Information, Information Technologies and on the Protection of Information" and No. 323-FZ "On the Fundamentals of Public Health Protection in the Russian Federation". On 7 June 2025 the President of Russia signed Federal Law No. 150-FZ[8], the amendments will enter into force from 1 September 2025, in particular:

- The Russian Government will be granted the right to establish criteria on the quality and effectiveness of Supplements, the specifics on regulating their application, as well as their registration, etc.;

- Information with proposals on retail trade in prohibited supplements, *inter alia*, remotely, may be included in the Unified Register of Domain Names, Web Page Links and Network Addresses Making it Possible to Identify Websites Containing Information Whose Dissemination in the Russian Federation is Prohibited;

- Healthcare professionals will be entitled to prescribe the registered Supplements included in the respective list, provided that there are instructions on applying them.

2. Antitrust regulation

2.1 Case of OOO KRKA-RUS vs the Federal Antimonopoly Service of Russia[9].

Facts of the case

The Commission of the Federal Antimonopoly Service of Russia, after considering case No. 33/01/10-1/2024, declared that the actions of OOO KRKA-RUS ("**KRKA-RUS**") on increasing the price of the medicine Co-Dalneva (International Nonproprietary Name ("**INN**") Amlodipine+Indapamide+Perindopril) constituted a breach of antitrust legislation and issued an order on the termination of the breach.

KRKA-RUS filed a petition with the Commercial Court of the City of Moscow against the Federal Antimonopoly Service of Russia on declaring the decision and order illegal. The petition was dismissed.

Position of the court

The court agreed with the conclusion of the Federal Antimonopoly Service of Russia that KRKA-RUS holds a dominant position on product markets with products that are not interchangeable: it committed an abuse of its dominant position with the medicine Co-Dalneva in four different dosages by establishing monopoly high prices for Co-Dalneva in connection with the following:

- The change in the expenses required to manufacture and sell the goods is at variance with the change in the price of the products.

The increase in expenses, depending on the dosage of the medicine Co-Dalneva, ranged from 1% to 11%, with price growth ranging from 10% to 16%. The simultaneous increase in profit ranged from 19% to 2,344%;

- The actual sellers and buyers of the product and the terms and conditions governing the circulation of the product on the product market remained unchanged.

The court rejected the arguments of KRKA-RUS that all the medicines with an identical INN, regardless of the dosage, were interchangeable, stating that in the specific instance where one concludes that a medicine is interchangeable, it must be possible to use, instead of the medicine

with one TIN in a specific dosage, a medicine with the same TIN, but in another dosage.

Importance of the case for business

Deputy Head of the Federal Antimonopoly Service of Russia Mr Nizhegorodtsev articulated the regulator's intention to tackle any unsubstantiated increase in prices for medicines that are not included in the list of essential and most important medicines. Furthermore, the Federal Antimonopoly Service intends to use the model for conducting a check that was used in the case with KRKA-RUS[10].

On 4 June 2025 KRKA-RUS filed an appeal against the decision of the court of first instance. We will monitor subsequent developments in this case.

2.2 AO AKRIKHIN vs the Federal Antimonopoly Service of Russia. The court confirmed the infringement of the exclusive rights of AstraZeneca AB.

On 15 May 2025 the Commercial Court of the City of Moscow issued a decision in case No. A40-305697/2024 on declaring illegal the decisions and orders of the Federal Antimonopoly Service of Russia regarding its conclusions on the transfer to the federal budget of the income of AO AKRIKHIN in the amount of approximately RUB 578 million, which had been obtained as a consequence of a breach of antitrust legislation.

Background

AstraZeneca AB (Sweden) and OOO AstraZeneca Pharmaceuticals (Russia) filed a petition in April 2024 with the Federal Antimonopoly Service of Russia on declaring the actions of AO AKRIKHIN (Russia) regarding the import from Poland to Russia and sale in Russia of the medicine Fordiglif an act of unfair competition.

The petition was attributed to the fact that AO AKRIKHIN had through the import and sale of Fordiglif infringed upon the exclusive right to the invention under patent No. 2746132 which was owned by AstraZeneca AB.

In its decision[11] the Federal Antimonopoly Service of Russia declared that the actions of AO AKRKIKHIN on introducing Fordiglif into circulation constituted the illegal use of the invention C-aryl glucoside SGLT2 inhibitors and method under complementary patent No. 2746132 and qualified its actions as a breach of Article 14.5 of the Competition Law. The Federal Antimonopoly Service of Russia also issued an order in respect of the Applicant,[12] in which it demanded that the company stop introducing Fordiglif into circulation until the term of the patent protection

of complementary patent No. 2746132 had expired (15 May 2028), and also transfer to the federal budget the income that it had derived as a consequence of the breach of antitrust legislation in the amount of RUB 577,704,312.

AO AKRKIKHIN disagreed with the decision and order of the Federal Antimonopoly Service and applied to court.

Position of the Commercial Court of the City of Moscow

The court agreed with the conclusions of the Federal Antimonopoly Service of the Russia that the invention under complementary patent No. 2746132 of AstraZeneca AB had been used illegally in Fordiglif. Accordingly, the actions of AO AKRIKHIN on introducing Fordiglif into circulation constituted a breach of antitrust legislation.

At the same time, the court held that the Federal Antimonopoly Service of the Russia should have calculated a turnover fine, instead of imposing sanctions in the form of the transfer of the income of AO AKRIKHIN to the budget in the amount of approximately RUB 578 million, and accordingly overturned the acts of the Federal Antimonopoly Service of the Russia in this respect.

Important citations of the court

- "*The use of intellectual property without the authorisation of the rights holder not only runs contrary to the law, but also clearly ensures preferential treatment compared to other market participants – competitors which are incurring corresponding expenses in good faith and also refrain from introducing products into circulation in breach of civil legislation*."

- "*Non-compliance with effective legislation poses a threat* to *public interest*."

- "*The Eurasian Pharmaceutical Register only performs an information function. Consequently, the inclusion of information therein does not serve as grounds for drawing conclusions on the onset of legally significant events regarding both an actual invention and also its rights holder*." At the same time: "*The Pharmaceutical Register contains up-to-date, truthful and comprehensive information on inventions pertaining to the pharmacologically active substances included based on an expert examination conducted by the Eurasian Patent Office*."

2.3 Refusals of pharmaceuticals companies to conclude supply contracts

The antitrust authority has not been overlooking the appeals of distributors in connection with the refusals of pharmaceuticals companies to conclude contracts on supplies of medicines. Recently we have witnessed an increase in the number of warnings issued by the Federal Antimonopoly Service on the need to delete discriminatory provisions from the commercial policies of companies.

In May 2025 the Federal Antimonopoly Service of Russia reported[13] that it had issued a warning to OOO Angelini Pharma Rus on the need to delete from its commercial policy unsubstantiated requirements on the minimum market share and the minimum annual volume of procurements on the part of a distributor. This was triggered by an appeal filed by OOO Pharmkomplekt in connection with the company's refusal to conclude a contract on the supply of the medicine Tantum Rosa.

Previously in April 2025 the antitrust authority had already issued a warning to OOO Swixx Healthcare in connection with the requirements of the commercial policy on the distributor's revenue, the latter's experience of participating in state procurements[14], and also to OOO Amgen regarding its requirements on the distributor's revenue[15].

3. Intellectual property: case of NOVO NORDISK A/S vs the Russian Government

The Supreme Court of the Russian Federation dismissed the petition of the Danish pharmaceutical company NOVO NORDISK A/S on contesting a number of the directives of the Russian Government which permitted the use of the patents of NOVO NORDISK A/S, which are being used to manufacture the medicine Semaglutide.[16]

Certificate on the application law of regulation

Pursuant to Article 1360 of the Civil Code of the Russian Federation (the "**Russian Civil Code**"), the Russian Government is entitled to adopt a decision on the use of an invention, utility model or industrial prototype without the consent of the rights holder in case of emergency and for narrowly defined purposes:

- to guarantee national defence and safety or
- to protect the lives and health of individuals.

This norm is not an intrinsically Russian trait.

At an international level the legal grounds for the use of patents without the consent of their rights holders are provided by Article 31 of the Agreement on Trade-Related Aspects of International Property Rights ("**TRIPS**")[17] which allows member nations to consolidate in legislation

the use of the subject matter of a patent without the authorisation of the rights holder, including use by the state or third parties duly authorised by the state, subject to compliance with specific criteria.

Russia is a member nation of TRIPS and this document has been in force in Russia since 22 August 2012.[18]

In practice the Russian Government has already exercised its right to issue authorisations on the use of inventions without the consent of the rights holder on several occasions (for example, regarding the patents of Gilead Sciences, Inc., and Gilead Pharmasset, LLC in 2020-2022).

At the end of 2023 the Russian Government authorised the Russian Limited Liability Company Geopharm and Limited Liability Company Promed Rus to use inventions protected by Russian patents owned by the Danish company Novo Nordisk A/S in order to provide the Russian population with medicines with the International Nonproprietary Name Semaglutide.[19]

Facts of the case

The current decisions were adopted in connection with a notice of Novo Nordisk A/S in 2022 issued to the Federal Service for Surveillance in Healthcare on the termination of supplies of medicines to Russia with an active substance with INN Semaglutide under the trade names Ozempic® and Rybelsus®.

The current authorisations of the Russian Government regarding the inventions of Novo Nordisk A/S are No. 3286-r and 3930-r, dated respectively 15 November 2024 and 21 December 2024.

These directives authorised the Russian limited liability companies OOO PSK Pharma and OOO Promomed RUS to use a series of inventions of Novo Nordisk A/S until 31 December 2025 inclusive, without the consent of the rights holder in order to provide the Russian population with Semaglutide.

The rights holder Novo Nordisk A/S filed claims with the Supreme Court of the Russian Federation, where it challenged the indicated directives of the Russian Government. The company cited the fact that one patent had been annulled, while the other patent did not pertain to Semaglutide and is being used instead by the rights holder in a medicine to tackle obesity, accordingly, the directive of the Russian Government is impeding the commercialisation of this medicine.

In view of the above, the rights holder held that the terms and conditions for the issue of an authorisation under Article 1360 of the Russian Federation had been violated by the Russian Government, there was no

emergency for the Russian Government, a notice on compensation for the use of the patents had not been submitted to the rights holder. However, the Supreme Court of the Russian Federation sided with the Russian Government.

Important citations of the court

After considering the case, the Supreme Court of the Russian Federation drew the following conclusions:

- "Legislation […] does not contain exhaustive characteristics or an exhaustive list of emergencies";
- "The insufficient accessibility of the full range of a medicine or medical product for the inhabitants of the country, medical or other organisations, serves as sufficient grounds for declaring this incident to be an emergency related to the protection of the lives and health of individuals";
- The contested directives of the Russian Government "do not place restrictions on the turnover of patented medicines and do not prevent […] the claimant from doing business in the Russian Federation".

Should you have any questions regarding the protection of the rights of foreign companies in Russia and in CIS countries and in the Eurasian Economic Union, rest assured that ADVANT Beiten is always at your disposal.

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[1] Judgment No. 13AP-8718/2025 of the Thirteenth Commercial Court of Appeal dated 23 May 2025 in case No. A21-7985/2024.

[2] Ruling No. S01-731/2025 of the Intellectual Property Court in case No. A21-4334/2024 "On Agreeing to Consider the Cassation Appeal and on Scheduling a Court Hearing".

[3] Judgment No. F04-1156/2025 of the Commercial Court of the West Siberian District dated 29 May 2025 in case No. A81-7030/2024.

[4] Judgment No. F04-1079/2025 of the Commercial Court of the West Siberian District dated 27 May 2025 in case No. A03-7678/2024.

[5] Judgment No. F04-964/2025 of the Commercial Court of the West Siberian District dated 19 May 2025 in case No. A27-10481/2024.

[6] Judgment No. F02-1212/2025 of the Commercial Court of the East Siberian District dated 12 May 2025 in case No. A19-18385/2024.

[7] Draft Law No. 638771-8 "On the Introduction of Amendments to Individual Legislative Acts of the Russian Federation (regarding Improvements to the Regulation of the Circulation of Nutritional Supplements)".

[8] Federal Law No. 150-FZ dated 7 June 2025 "On the Introduction of Amendments to Individual Legislative Acts of the Russian Federation".

[9] Decision of the Commercial Court of the City of Moscow dated 5 May 2025 in case No. A40-297158/24.

[10] https://xn--90aivcdt6dxbc.xn--p1ai/articles/news/fas-proverit-prichiny-rosta-tsen-na-lekarstva/.

[11] Decision of the Federal Antimonopoly Service of Russia in case No. 08/01/14.5-65/2024 dated 11 November 2024.

[12] Order of the Federal Antimonopoly Service of Russia in case No. 08/01/14.5-65/2024 dated 11 November 2024.

[13] https://fas.gov.ru/news/33994.

[14] https://fas.gov.ru/news/33948.

[15] https://fas.gov.ru/news/33932.

[16] Decision of the Supreme Court of the Russian Federation dated 6 May 2025 in case No. AKPI25-102.

[17] Concluded in Marrakesh on 15 April 1994.

[18] Collected Legislation of the Russian Federation, 10 September 2012, No. 37.

[19] Directive No. 3937-r of the Government of the Russian Federation dated 27 December 2023

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