

Supreme Court upheld Federal Antimonopoly Service in dispute on unlawful market launch of generic drug

In 2024, the Federal Antimonopoly Service (the “FAS”) issued several decisions in favour of originator companies in response to their complaints on unlawful circulation of generic products before expiration of patent protection for the brand-name drugs. Initially, this seemed to be a new and effective strategy for protecting the originators’ interests.

However, in 2025 the trend shifted. Generic companies succeeded in challenging the FAS’s decisions. Courts consistently overturned orders against companies marketing generic “[Axitinib](#)”, “[Osimertinib](#)”, “[Ruxolitinib](#)”, and “[Bosutinib](#)”. As a result, by the end of the year the industry concluded that a pro-generic approach had already become a stable judicial practice*.

However, the situation changed again this March, when the dispute on “Axitinib” was [examined**](#) by the Russian Supreme Court. In its decision, the Supreme Court upheld the antimonopoly authority, which had previously initiated proceedings against “Axelpharm” under the complaint of the originator, and ordered “Axelpharm” to transfer RUB 514m (approx. EUR 5,5m) to the state budget.

The Supreme Court’s ruling formulates legal positions that sharply contrast with the pro-generic approach previously formed in the lower courts. The comparison of the positions on the most significant issues is set out in the table below.

Issue	Positions of Lower Courts	Position of the Supreme Court
Whether the existence of competitive relations between a patent holder and an infringer is a mandatory condition for qualifying the latter’s actions as unfair competition?	Yes	No
	For the application of Article 14.5 of the Federal Law “On Protection of Competition” the existence of competitive relations directly between an infringer and a patent holder must be established (Decision of the 9 th Appeal <i>Arbitrazh</i> Court as of 16.12.2025 , and as of 15.12.2025).	An infringement of IP rights may be recognised as unfair competition not only in cases where a patent holder directly competes with an infringer, but also in other cases of causing harm to rightsholder’s interests.

	No	Yes
Is it possible to ascertain the use of an invention on the basis of indirect evidence?	<p>Patent expertise is mandatory for ascertaining the use of an invention (Decision of the Arbitrazh Court of Moscow as of 27.11.2025).</p> <p>An administrative authority's decision based on assumptions or conjecture is unlawful (Decision of the 9th Appeal Arbitrazh Court as of 15.12.2025).</p>	<p>Obligation to conduct patent expertise leads to an unreasonably high standard of proof.</p> <p>A finding of infringement of IP rights may be made by the FAS based on cumulative evidence: specialists' reports, facts ascertaining the circulation, extracts from the Eurasian Pharmaceutical Register, etc.</p>
Can preliminary actions aimed at the lawful use of an invention (for example, applying for a compulsory licence) prove the use of an invention?	<p>The choice of legal remedies cannot prove an infringement (Decision of the 9th Appeal Arbitrazh Court as of 16.12.2025).</p>	<p>The FAS lawfully ruled that preliminary actions (such as submitting a licence offer, filing a claim for a compulsory licence, etc.) may be qualified as acknowledgement of infringement.</p>
Is the FAS competent to independently examine unfair competition cases related to the unlawful use of intellectual property?	<p>Some courts noted that the antimonopoly authority is not competent to resolve the cases involving patent infringement (Decision of the 9th Appeal Arbitrazh Court as of 17.07.2025).</p>	<p>The Supreme Court has not commented on this issue directly, but the FAS's decision would hardly have been upheld if the service had not originally had the competence.</p>

The Supreme Court's position can change the pro-generic approach established in judicial practice. Following the Supreme Court's decision, in the dispute concerning "Osimertinib" the cassation instance has already [overturned](#) the lower courts' decisions, ruling in favour of the FAS. In April, there will also be appeal hearings regarding the disputes on "Ruxolitinib" and "Bosutinib".

The Supreme Court's position may encourage patent holders to more actively use the antimonopoly track of protecting their interests. Considering the balance of outcomes, speed, and costs, this mechanism may be more efficient than traditional court litigation.

* We have previously overviewed the history of unfair competition disputes between originator and generic companies. Our materials on this are available at the following links: [\[1\]](#), [\[2: p. 10\]](#).

** All links to judicial documents are in Russian.

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Our team stands ready to offer full legal assistance on all issues concerning business operations in Russia.



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