



IP Court interpreted IPR protection provisions stipulated in the Federal Law "On Circulation of Medicines"

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SPEED READ

Pursuant to Article 32(7) of the Federal Law "On Circulation of Medicines"¹, a court decision confirming the violation of intellectual property rights (IPR) may serve as grounds for the cancellation of a registration certificate of a medicine. This rule is aimed at protecting the exclusive rights to innovative pharmaceutical products. The rule does not distinguish the legal nature of the court's decision, confirming the IPR violation. However, on 20 September 2016, in Case No. A40-158999/2015, the Intellectual Property Court (IP Court) gave a narrow interpretation to this provision, limiting the opportunity of innovative manufacturers to claim the annulment of a registration certificate for follow-on/"violating" product.

BACKGROUND

A local distributor (further the Distributor) was selling in Russian regions a flu medicine manufactured in the Republic of Belarus. The active ingredient used in this medicine was protected by Eurasian Patent No. 008765. The patent belonged to a pharmaceutical company, which was a direct competitor of the Distributor, and was selling its own medicine having the same active ingredient.

The antitrust service qualified the sales of the patented product by the Distributor as being in violation of IPR of its competitor, and thus unfair competition. The Distributor filed a court claim to annul the decision of the antitrust service. However, in Case No. A43-18360/2013, the court confirmed the conclusions on unfair competition.

Based on this court decision, the patent holder applied to the Ministry of Health (further the MoH) with a claim to annul the registration certificate of the relevant

flu medicine, sold by the Distributor, and exclude this medicine from the State Register of Medicines. The MoH rejected the claim as groundless, and so the patent holder applied to the court.

IP COURT FINDINGS

The court of first instance and the appellate court rejected the claim. The IP Court confirmed the findings of the lower courts, based on the following.

The IP Court concluded that the court decision, which pursuant to Article 32(7) of the Federal Law "On Circulation of Medicines" may serve as grounds for cancellation of a registration certificate, must be awarded through an IPR/patent dispute, and not through an administrative dispute (e.g., related to unfair competition).

As the patent violation of the Distributor was confirmed in the administrative (antitrust) proceedings, the IP Court ruled that, it was not enough for the MoH to apply Article 32(7) of the Federal Law "On Circulation of Medicines" and annul the registration certificate of the relevant flu medicine.

CONCLUSIONS AND RECOMMENDATION

The IP Court gave a conservative interpretation of Article 32(7) of the Federal Law "On Circulation of Medicines". In the future, this interpretation may narrow the mechanisms of IPR protection for innovative medicines, laid down in the law. At the same time, this court case clearly demonstrates that administrative antitrust proceedings should not be mixed with IPR protection disputes. If applied by analogy, this principle means that IPR related regulatory activity may not be based on the practice developed within the framework of competition protection.

¹ Federal Law No. 61-FZ dated 12 April 2010 "On Circulation of Medicines" (as amended).

Contacts



ALEXANDRA VASYUKHNOVA

Partner, Head of Technology
and Investment group

vasukhnova@vegaslex.ru



DMITRY BORODIN

Associate of Technology
and Investment group

borodin@vegaslex.ru

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