

The Rospatent cancels Pfizer pharma patent at the request of Russian generic producer

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Russian pharma producer “PSK Pharma” has been successful in patent cancellation proceedings instituted against US Pfizer at the Rospatent, with respect to pharmaceutical active principle tofacitinib (Janus kinase group inhibitor) used for treatment of rheumatoid arthritis and other affections in pharmaceutical product under trade name Jaquinus, which was registered in Russia in 2013. The grounds for cancellation put forward by the Russian company were that the initial patent application did not contain some contents featuring in the granted patent claims (added matter) and that the patent claims did not present the necessary requisites of novelty, inventive step and industrial applicability.

The patent cancellation request was a counter-action to oppose the infringement claim brought by Pfizer against the Russian company. Around the beginning of 2020, PSK Pharma had applied for a drug registration for a generic version of Jaquinus (under trade name Tofara). Pfizer claimed

infringement of its Eurasian patent on tofacitinib before the Moscow Arbitrazh Court, that in December 2021 enjoined the sale of Tofara until expiry of the Pfizer patent in November 2025. The Russian company appealed the first instance decision, and the appellate decision on infringement is awaited.

Patent cancellation decisions of the Rospatent can be challenged before the Russian Intellectual Property Court, and Pfizer told the Russian press that they will file an action aimed at setting aside the Rospatent.

This is a rare case of cancellation of a foreign pharmaceutical company patent by the Rospatent. Other relatively recent similar attempts to cancel pharma patents of Gilead Sciences and Johnson & Johnson were rejected.

The cancellation of the patent is a new circumstance capable of affecting the infringement case between Pfizer and PSK Pharma on the tofacitinib generic version, and may constitute a ground for

reversing the first instance judgment on appeal.

It is worthwhile noting that this case has nothing to do with the recent legislation that has affected IP rights owned by foreign companies from “unfriendly countries” enacted in Russia in the wake of the Ukrainian crisis. Generic entrants that challenge the patents of the

originators in an attempt to gain premature access to the market are a common feature to all jurisdictions of the world, and there seem to be no known indicators that the PSK Pharma/Pfizer dispute was influenced by non-legal considerations. The case is of great interest to the entire pharma industry and we will provide regular updates in due course.



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