

## Moscow Region Commercial Court rendered a precedent decision in an originator-generic dispute

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On September 27, 2017, the Moscow Region Commercial Court published a significant [decision](#) in a patent dispute between Novartis AG, Swiss originator, and Nativa LLC, Russian generic producer (case No. A41-85807/2016).

Under the auspices of the case, Novartis AG filed a patent infringement lawsuit against Nativa LLC claiming that its active patent on «Tyrosine kinase inhibitors» (No. 2348627) is used both in the “original” drug “Tasigna” and “generic” drug “Nilotinib-native”<sup>[1]</sup>, while registration of the “generic” drug before the Ministry of Health threatens to violate the patent.

The lawsuit was partially satisfied: the first-instance court (1) recognized the use of the patent in the opposing drugs and (2) prohibited the defendant to market the “generic” drug until the patent expires.

This decision is definitely positive for patent protection in Russia.

Previously, Russian courts tended to dismiss such claims based on that (1) registration is just a “preparatory” action that cannot *de jure* infringe a patent, and (2) any patent use prohibition “for the future” does not comply with Russian legislation.

Although in 2009 Novartis AG won the same case against another generic company<sup>[2]</sup>, courts have become very reluctant to decide in the same way.

For instance, recently the Moscow Region Commercial Court rejected Bristol-Myers Squibb Holdings Ireland’s lawsuit against Nativa LLC<sup>[3]</sup>. The court found that the defendant’s attempt to register its generic drug should rather be classified as a “preparatory” action, which does not constitute an infringement and should not entail other negative consequences (*inter alia* prohibition “for the future”).

Thus, we believe that the decision in *Novartis AG vs. Nativa LLC* could evidence that court practice is slightly shifting towards more secured patent protection.

In a view of the recent Government initiative to disclose all incoming applications for registration of drugs (such information is still confidential in Russia) and to supplement the official drugs register with patent information, we believe that patent protection may significantly strengthen and get closer to the classic “patent linkage” system. Such amendments will surely make the system more predictable and effective for investors, state watchdog and patients.

<sup>[1]</sup> Both drugs have the same INN – Nilotinib.

<sup>[2]</sup> *Novartis AG vs. Pharm-Sintez CJSC*, Supreme Court Decision dated June 16, 2009 in case No. A40-65668/2008.

<sup>[3]</sup> *Bristol-Myers Squibb Holdings Ireland vs. Nativa LLC*, Moscow Region Commercial Court Decision dated May 19, 2017 in case No. A41-7505/2017.

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