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Russia: On a slow boat to patent linkage?

Boris Malakhov (Lidings) · Wednesday, May 22nd, 2019



Russian law provides that information on state registration of drugs shall be publicly available.

For a long period, MoH used to turn a blind eye to this obligation, keeping information on all filed applications confidential. Absence of this information used to pose additional risks for patent holders lacking information on the upcoming launches of generic drugs.

In April 2019, Russian MoH finally launched the section on [Information related to state registration](#) on its website. This section has disclosed information on recently filed applications for registration of drugs and currently pending before MoH.

Access to this information is particularly significant in harsh competitive conditions on the market and a significant increase of patent disputes in Russia between originators and generics.

Russian law does not recognize registration of generic drugs during the patent validity term as an act of infringement (Art. 1359 (2) of the Russian Civil Code, [Decision of the Supreme Commercial Court in case No. A40-65668/2008, dated 06.16.2009](#)).

However, disclosure of information on filed applications will allow patent holders to keep control of any threat of infringement coming from generic registrations. Under the current jurisprudence, a *threat of infringement* takes place when a generic drug obtains a market authorization in Russia over 3 years before the patent expiry (previous post [here](#)).

Moreover, MoH has prepared a draft version of the amendments to the [Law on Drugs](#). It says that

any company seeking to register a new drug (original or generic) shall indicate all patents and trademarks relevant for this new drug. Another obligation is to warrant that registration of this new drug would not infringe any third party's intellectual rights, under the risk of penalties.

Disclosure of information on filed applications as well as initiatives to formalize IP compliance in the process of registration of drugs will likely to strengthen the legal protection of patent holders against malicious practices in Russia.

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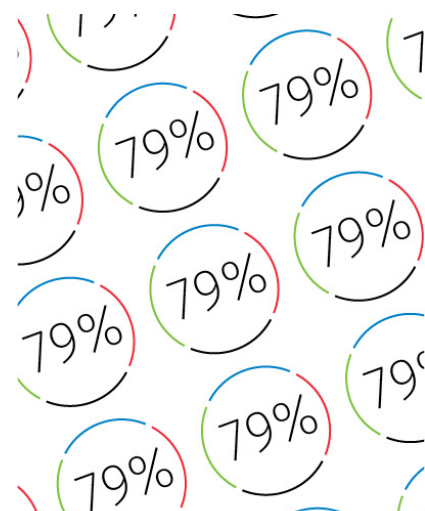
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