Ministry of Health of the Russian Federation submits amendments to the Law “On Medicine circulation” introducing a Pharmacologically Active Substances Register

16/09/2019 INTELLECTUAL PROPERTY, RUSSIA, PHARMACEUTICALS AND LIFE SCIENCES

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The Ministry of Health of the Russian Federation introduced a draft regulation of Pharmacologically Active Substances Register within suggested amendments to the Law “On Medicine circulation”. The Register will be maintained by the Russian PTO, and information recorded in the Register will be open to the public. Recording an active substance in the Register will not be mandatory for patent owners, and will be subject to filing an application and payment of a fee. Before including the substance into the Register, the Russian PTO will review the application and determine if the active ingredient protected by the patent that is at stake is covered by the product marketing authorization. The Russian PTO advised that the main purpose of the Register is to improve the governance of generic products.

Currently, Russian law does not restrict the issuance of marketing authorizations for generic products, but prohibits their marketing during the term of the basic patent for the originator product. The marketing authorization for the generic product can be sought and obtained without restrictions during term of the basic patent for the originator product. The Russian courts do not consider seeking and receiving a marketing authorization a form of use of the patent for originator product. Once the marketing authorization is issued, the company can start production and sales of the product. The only possible way to

protect the originator's patent rights against the marketing of the generic product is to file a suit claiming that production and marketing of the generic product infringes the patent rights of originator, and asking an injunction. The amendment was introduced after several cases, where the generic product entered the Russian market infringing the patent rights protecting originator products of big pharma companies (e.g. case A41-87845/17 Bristol-Myers Squibb v. NATIVA).

The amendment is intended to suspend the marketing of generic products. The application for the marketing authorization will still be allowed and the authorization can be granted, but the marketing authorization for the generic version of the originator product listed in the Register will become effective only after the expiry of the patent that comprises the originator product.

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