Russian authorities plan to curtail monopolies of pharma companies by banning or restricting the subsequent patenting of different forms of known medical substances

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It is well known that pharmaceutical companies tend to use all lawful opportunities to extend the term of protection of patented medical substances, and in that way sometimes delay generics market entry. One option is an extension of the patent term, which is available to counterbalance regulatory delays occurring in the marketing authorization issuance. Another – again, per se lawful – option is the subsequent patenting of different uses, compositions or pharmaceutical forms of the same substance. In that way, when the first patent for the original substance expires, the protection under the subsequent patents may be still ongoing (so-called “greenfielding”).

In accordance with current Russian law, not otherwise than in most other systems (including that of the European Patent Convention – EPC), a patent can be granted for a product or a method, including the way of use of a product or a method for a specific purpose (article 1350 of the Civil Code of the Russian Federation).

The Rules for drafting, filing and examining patents (Rules) describe in detail the procedure of examination of patent applications, including the assessment of patentability requirements of novelty, inventive step and industrial applicability, which may comprise second use, composition and pharmaceutical form patents.

The Russian Ministry of economic development announced the forthcoming issuance of amendments to the Rules, aimed at limiting to some extent the patentability of pharmaceuticals, and advised that after adoption of the amendments a patent may well not be granted for a chemical substance, which is a different form or a derivative of an existing substance known in the prior art.

The representative of the Ministry furthermore indicated that the amendments should accelerate the entry of generics into the Russian market, which may contribute to decreasing the prices for medicinal products and the overall pharmaceutical spend.

Neither the proposed wording, nor the timeframe for adopting the amendments were announced. It is unclear if amendments to primary Russian law will in turn need to be introduced in order to make the new Rules lawful, which is at present a debated issue.

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