Subsequent patenting of different forms of known medical substances in Russia may be curtailed in the future

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Earlier this year, the Russian Ministry of economic development announced its plans to limit the subsequent patenting of different forms of known chemical substances, and thus encourage generic drugs entry into the Russian market. The stated purpose of this policy is the triggering of a decrease of retail prices of pharmaceutical products.

It is common grounds that the subsequent patenting of different forms of known medical substances (so-called “evergreening”) is often relied on by pharmaceutical companies in order to extend the length of patent protection, and also in that way offset the delay of the commercial launch of medicinal products caused, besides by the time needed for development, by the regulatory delays involved by clinical trials and obtaining of the marketing authorization. This may considerably reduce in practice the nominal twenty-year duration of the exclusive right.

Article 1350 of the Civil Code of the Russian Federation foresees the grant of a patent for a product or a method, including the way of use of a product or a method for a specific purpose. This general rule was elaborated in regulations of the Ministry, which contain the details of the requirements of patent applications as well as the relevant procedure and substantive examination.

On 31 March 2021, the Ministry issued order no. 155 introducing amendments to the Rules for application and grant of patents for inventions (Rules) and to the Requirements of patent applications (Requirements).

Both instruments relate to new forms of existing chemical substances. They do not totally ban their subsequent patenting, but considerably restrict such

option by a number of special requirements.

More particularly, item 77 of the Rules contains a list of categories of inventions that are considered not meeting the inventive step requirement. The recent amendment expands the list adding inventions based on chemical substances in the new form of existing chemical compositions, in particular, in the form of an isomer, a stereoisomer, an enantiomer, an amorphous or crystalline form, or a derivative of an existing chemical composition, namely, a salt, a solvate, a hydrate, a complex molecular compound or ether, but for the cases where such new form shows new quantitative or qualitative characteristics that are not obvious to the skilled person from the state of art.

This new approach also affects the standard of compliance with the industrial applicability criterion as reflected by the patent application materials set out in item 47 of the Requirements. Part 6 of such provision provides that the materials in support of an application for a new form of an existing chemical substance shall include information showing the non-obvious nature of the new quantitative or qualitative characteristics, and shall comprise evidence proving the proving their existence and performance thereof. Besides, an application claiming a biological activity level of a new form for the diagnosis, treatment or prevention of diseases shall include true relevant information proving the effect of the substance form or derivative on aetiopathogenesis, body condition or its connection with the diagnosis. Such proof of industrial applicability can be based on various types of information and evidence, including those obtained during test on a relevant pattern/model.

The Russian press reported that representatives of the pharmaceutical industry expressed concern that the amendments will prejudice the rights of inventors of original medicinal products and will result in adverse consequeneces for Russian innovative pharmaceutical companies, which are frequently – and necessarily - focused on the development of new forms of existing medicines.

Legal community has expressed a variety of opinions on the subject, but mostly does not quite perceive the amendments as undermining patent protection in general, and rather see them as helpful tools to counter evergreening.

One could say that the new rules on the characteristics of a new or derivative forms of a chemical substance for patenting purposes largely correspond to the inventive step requirement. Applicants for such patents were already expected to show the advantages produced by the invention at the substantive examination stage with the Rospatent, as a demonstration of inventive step. In turn, the existence of claimed characteristics was always required to be proved and disclosed in the supporting materials of the application. Conversely, the amendments will not affect the novelty requirement (or the inventive step and industrial applicability requirements in other regards).

In other words, the new wording of the Requirements does not prohibit the subsequent patenting of the form or derivative, but make sit explicit that such form or derivative must demonstrably provide some benefit to the solution of the technical problem. This is likely to be in line with the general aim of intellectual property and the striking of a balance between the exclusive right of the patentee in order to stimulate research, progress and technical advancement, and the general interest in averting the creation of unjustified monopolies.

Finally, only the concrete application of the new text of the Rules and the Requirements for the examination of new forms and derivatives of chemical substances and the outcomes of the latter will tell if the new approach in fact altered the previous decision-making practice of the Rospatent in the sense of a stricter assessment of the subsequent patenting of new features of known chemical substances.

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