



Extension of patent term in Russia. Legal requirements and case law

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📌 INTELLECTUAL PROPERTY, RUSSIA, PHARMACEUTICALS AND LIFE SCIENCES

Alisa Pestryakova

The possibility to extend the term of a patent for a pharmaceutical invention is not set out in any international agreement; however, it is available in many countries including the EU member States. The idea behind the special treatment of pharmaceutical patents is to compensate regulatory delays and encourage research by extending the effective protection in a way sufficient to compensate investments for research, development and trials.

In line with the position of countries providing additional protection for pharma patents, the Russian Civil Code includes a provision allowing the extension of the patent term (Article 1363 of the Russian Civil Code). The current version is the result of a Civil Code amendment adopted in 2014. It defines the following requirements for the extension of patent term.

- A. Term extension is applicable not only to patents for pharmaceutical products but also for pesticides and agricultural chemicals that are subject to obtaining a previous marketing authorization.
- B. The term extension can be granted in case the first authorization for use of a pharmaceutical, a pesticide or an agricultural chemical was obtained later than five years from the patent application date for the product.
- C. In order to avail itself of the term extension the patent owner shall file an application with the Russian PTO within the validity period of the patent and not later than six months from the date of the first marketing authorization for the product protected by the patent or the date of patent grant, whichever expires later. This sets the deadline for filing the application:
 - Within the patent term, and



- Within 6 months from the date of first marketing authorization, or
 - Within 6 months from the patent grant date.
- D. The patent protection period is extended by the period lapsed from patent application date till the date of grant the first marketing authorization for the product, minus 5 years. The maximum extension term is 5 years.
- E. The Russian PTO may ask the patent owner to provide additional documents needed for the assessment of the application and in case of failure to provide these within 3 months (such deadline can be extended up to 10 months) the application is rejected.
- F. The extended term of the patent is limited to the claims of the patent featuring the product having obtained the marketing authorization. If the extension is granted, an additional patent letter is issued for the claims pertaining to the pharmaceutical, pesticide or agricultural chemical authorized product. Russian law does not set out any other requirements in connection with the extension of patent term.

A procedure before the Russian PTO for patent term extension was adopted by the Russian Ministry of Economy in 2015, specifying timeframe and required documents. In accordance with the procedure, the following documents are prescribed:

- An application form signed by patent owner or all patent owners or representative(s);
- Patent claims that pertain to the authorized product;
- Power of attorney in case the application is signed by representative(s);
- Consent of all persons listed in the application to personal data processing;
- Marketing authorization for pharmaceutical product and information on recording of the product in the State Register of Medicines or marketing authorization

for pesticides and agricultural chemicals.

The relevant official fee shall be payable on filing of the application. The applicant is not obliged to provide an official payment confirmation, or the marketing authorization together with the application. The Russian PTO will obtain the necessary information from other authorities.

Within 60 working days the Russian PTO either grants a patent extending the term of the claims pertaining to the product or rejects the application.

During 2015-2017 the Russian IP Court adjudged several disputes in connection with patent term extension issues.

In 2015, the IP Court as cassation instance adjudged the objections of two companies against the extension of the term of a patent of Pfizer Inc. for a pharmaceutical substance (cases SIP-17/2015, SIP-308/2015). The claimants were arguing that the first marketing authorization was already used as the basis for the extension term for another patent of Pfizer, and should not be used again for another patent extension. Both patents of Pfizer pertained to the same substance Voriconazolium and the same pharmaceutical product Vfend. Due to the extension of the second patent of Pfizer, generics entering the Russian market were delayed for additional 18 months. The claimants considered the grant of patent extension term unlawful and asked for cancellation of second extension.

In both cases the Court held that only two requirements for term extension were foreseen by the law: 1) the application must be filed within the term of the patent and not later than six months from the date of the marketing authorization; 2) the invention must pertain to the product that is the object of the first marketing authorization.

The Court confirmed that no other conditions were applicable, including limiting the number of patents that could be extended based on one marketing authorization, provided that patented

invention falls within the scope of the authorized product. During the proceedings, the Court found that the first authorization provided by the patent owner in support of its application for extension had been also relied for the extension of another patent of Pfizer. The Court, though, confirmed that this did not raise any problem, since the authorized product pertained to both patents. As a result, two patents of Pfizer benefitted from the extension based on one marketing authorization for one medicinal product.

This position differs from the European case law concerning supplementary protection certificates for medicinal products, which provides that the product must not have already been the subject of a certificate.

In another case, the Court upheld an objection to a term extension, finding that the marketing authorization relied on calculation of the deadline for filing the application was not the first authorization obtained for the product. The Court stressed that the Russian PTO has neither the means nor the obligation to check if the authorization provided by the patent owner is the first authorization for use of the product.

As a result, the extension of the patent term was cancelled, since the deadline of six months for filing the application had been missed by the patent owner, as calculated from the date of issuance of the first authorization.

The fact that the patent owner did not provide the first authorization for the product as the basis for the application for term extension, per se was not considered by the Court as the ground for cancellation of extension. Russian law does not prescribe that the documents be provided together with the application. The requirements only set a deadline for filing the application and the pertinence of claims to the authorized product.

The most recent case adjudged by the Russian IP Court as cassation instance in 2017 is case SIP-606\2016. The company Zoetis Services LLC was objecting to the refusal of the extension

of the term of its patent for “Microfluid Oil-in-Water Emulsions and Vaccine Compositions”.

The Court upheld the position of the Russian PTO and the first instance court that the description of the invention presented significant discrepancies with the composition of the veterinary medicinal product that was at stake. The first instance court had compared the characteristics of the patented composition with the active ingredients of the product, as well as analyzed examples in the invention description, and found that the composition of antigens in the description of the product was not disclosed in the claims or description of the patent. Namely, two strains of viruses listed in the description of the product were not mentioned in the patent description and claims.

The patent owner argued that the essence of the invention was the use of the several different antigens in the vaccine in the form of oil-in-water emulsion. Both the Russian PTO and the Court acknowledged that the core of the invention was the vaccine in the form of oil-in-water emulsion, but made clear it was crucial that only some antigens were mentioned in the description of the invention, not all those listed in the product description, and such antigens had been tested in the invention one at a time, not as a composition.

To sum up, the extension of patent term in Russia is available for pharmaceutical products, pesticides and agricultural chemicals, provided the patent owner files the application within 6 months from the date of the first authorization for use of the product protected by the patent. A new patent is granted for the claims corresponding with the authorized product for the maximum term of 5 year, calculated as a term passed from the patent application date till the date of obtaining the first marketing authorization for the pharmaceutical product, pesticide or agricultural chemical in excess of 5 years.



Alisa Pestryakova
ASSOCIATE



a.pestryakova@dejalex.com



+7 495 792 54 92



Ulitsa Bolshaya Ordynka 37/4
119017 – Moscow

MILANO

Via San Paolo, 7 · 20121 Milano, Italia
T. +39 02 72554.1 · F. +39 02 72554.400
milan@dejalex.com

ROMA

Via Vincenzo Bellini, 24 · 00198 Roma, Italia
T. +39 06 809154.1 · F. +39 06 809154.44
rome@dejalex.com

BRUXELLES

Chaussée de La Hulpe 187 · 1170 Bruxelles, Belgique
T. +32 (0)26455670 · F. +32 (0)27420138
brussels@dejalex.com

MOSCOW

Ulitsa Bolshaya Ordynka 37/4 · 119017, Moscow, Russia
T. +7 495 792 54 92 · F. +7 495 792 54 93
moscow@dejalex.com

