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The clue is in the case law

Russian law provides for patent term extensions for pharma patents, but it is not always clear on the finer details. Evgeny Alexandrov, Gorodissky & Partners, examines the case law.

Pharma patents are unique. Not only because the development of a new drug often involves the outlay of millions of dollars, but also because, unlike other patents which can be put immediately on the market, the new drugs must be tested in order to prove their safety. The life cycle of the new medicine is usually equal to, or exceeds, the patent validity term. The approval and registration of pharmaceutical patents usually takes 5 to 10 years after filing of the application. This means that the duration of the monopoly right to the respective invention may be reduced. The imbalance is compensated for in Russia by the patent term extension (PTE) institute.

Initially the PTE procedure was introduced in Russian Patent Law in 2003. Since 2008, it has been regulated by Article 1363 (2) of the Civil Code of the Russian Federation. The latest amendments to the Article entered into force on January 1, 2015.

According to the Article:

"if from the filing date of an application for the grant of a patent for an invention relating to such product as medicine, a pesticide, or an agrochemical, the use of which requires duly granted permission, and until the date of granting the first permission for its application more than five years have elapsed, the validity term of the exclusive right to the respective invention and the patent certifying this right shall be extended upon request of the patent holder by the federal executive authority for intellectual property. The said validity term shall be extended for a period counted from the filing date of the application for grant of the patent for the invention to the date of receipt of the first permission for the use of the invention, minus five years but not more that for five years. The request for extension of the term shall be submitted by the patent holder during the validity term of the patent within six months from the date of receipt of the permission for application of the invention or date of patent grant, depending on which expires later".

According to the amended law, the PTE is certified by a supplementary patent with the claims containing the features of the patented invention and characterizing the product for which the marketing authorization (permission) has been issued, in other words the PTE shall be directed to the marketed product only.

As follows from Article 1363 (2) of the Civil Code, the key date for calculation of the PTE is the *date of receipt of the first marketing authorization (permission)*. Unfortunately, the law does not provide any explanation from exactly which date the patent owner should calculate the six-months for filing the PTE application: from the date of actual receipt of the marketing authorization or from the date of registration of the medicine. It is understandable that the time difference between these two dates is often significant.

The clue is in the case law

In the absence of clear legal regulation the answer can be found in the relevant case law. In particular, in the judgment of the IP Court in the *Abbott GmbH&Co. KG* case (case No. SIP-81/2013). The patent owner claimed the PTE for a patent with the priority date October 14, 1994 (expiration date is October 7, 2015) on the basis of the first marketing authorization for a medicine, registered on December 12, 2011.

The PTE application was submitted with the Russian Patent Office on February 28, 2013 with the request to extend the validity of the patent until October 7, 2020 (in other words for 5 years). However, the PTO rejected the application because it considered the patent owner had missed the term for filing the request. This was because the PTO calculated the six months from the registration date of the medicine.

During the proceedings, the IP Court established that, according to the stamp of the Ministry of Health of the Russian Federation on the decision on registration of the medicine, the actual date of the receipt of the decision by the applicant was August 28, 2012.

Résumé

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Evgeny graduated from the Russian State Institute of Intellectual Property (Moscow) as a lawyer. In 2005 he became a PhD. He advises clients on IP issues, including copyrights and neighboring rights, patent, trademark and other IP related matters. He represents clients before commercial courts and courts of general jurisdiction, administrative and law enforcement bodies. He often participates in IP conferences as a speaker on IP issues and regularly publishes articles in Russian and international magazines and websites. He co-authored the Russian chapter of the publication "Trade secrets through the world" published by West Publishing House.

In this regard the IP Court ruled that the six-month deadline **starts from the date of the actual receipt of the marketing authorization,** in other words from August 28, 2012, **but not from the marketing authorization publication date.** On the basis of the IP Court's decision the Russian PTO reconsidered the PTE application and extended the patent for five years.

PTE procedure

In order to initiate the PTE procedure the applicant must provide documents confirming the marketing approval for its product and containing information about the product's structure and composition, sufficient that an expert could then attribute the invention to the product for which the marketing authorization has been issued. With regard to the marketing approval, a notarized copy of the first marketing authorization certificate issued must be provided, stating:

- the registration number and date;
- the international non-proprietary name (INN) of the active agent of the product; and
- the product's qualitative and quantitative composition.

With respect to the compound (group of compounds described by structural formula) the Russian Patent Office checks if it relates to the medicine for which the marketing authorization is issued by way of comparing the compound and active agent of the respective medicine. At that stage, the Patent Office checks whether there is information in the description of the invention to the effect that activity of the compound allows use of it in the medicine (in other words, if the compound is an active agent of the medicine).

In cases where composition needs to be considered, the Patent Office compares the characteristics of the patented composition and the composition of the registered medicine (purpose, makeup of the composition, dosage form if the same is provided in the claims). The invention shall be considered as relating to the medicine where its independent claim contains characteristics of the medicine mentioned in the marketing authorization.

The PTO can grant a PTE in respect of inventions covering group of compounds, which includes compound or composition of the medicine containing such compound. This would be determined on the basis of the above approaches.

Time limit for challenging a PTE

It should be noted that the PTE granted by the Patent Office can be challenged by a third party and a three-month limitation period is provided by the procedural law for filing this action. The term starts from the date when the applicant learned about the extension. Missing the term results in a dismissal of the claim (Article 198 of the Russian Commercial Procedure Code).

Russian case law gives an idea of which circumstances can be used for determining the date from which the three-month limitation period must be calculated.

In the *Micardis* case (No. 40-85716/10-15-720) KRKA d.d. challenged the PTE of the Boehringer Ingelheim Pharma GmbH & Co KG's patent. During the proceedings, the court established that the official publication on the granted PTE was made in the official bulletin of the Patent Office on February 20, 2007 while KRKA d.d. filed an appeal with the court on July 9, 2010. In this regard the Court dismissed the case and recognized that KRKA d.d. should have monitored the extension publications which are publically available and missed the limitation period for challenging the PTE. The decision was upheld by the Court of Appeals.

However, later decisions of the IP Court in other cases did not support this approach. For instance, in case No. SIP-155/2014 CJSC, Veropharm challenged the PTE of Aventis Pharma S.A.'s patent. The Court recognized that Veropharm had not miss the three-month term (despite the publication being made on June 20, 2013 and the lawsuit being filed on March 11, 2014) because Veropharm demonstrated that they actually learnt about the extension in January 2014 during preparation for another litigation with Aventis.

This second case also relates to the first marketing authorization issue. The law does not provide an explanation as to what 'the first marketing authorization' is. Basically, if the patent relates to a compound

per se, the first marketing authorization is the authorization that was first issued for a product comprising this compound as an active agent in any dosage form and, if the substance was manufactured in Russia, the approval for its manufacture.

According to the judgment of the IP Court, if the patent covers a group of compounds characterized by the Markush structure, the first marketing authorization issued for any compound of the group is considered to be the first marketing authorization with regard to the PTE procedure.

In another case, No. SIP-17/2015, a Russian generic company Canonpharma Production CJSC challenged the PTE of Pfizer Inc.'s paten. The IP Court recognized that the three-month limitation term started from the date when the patent owner sent a cease-and-desist letter to Canonpharma Production CJSC.

Selective inventions and first marketing authorizations

This case is also a landmark one, as it relates to selective inventions and the possibility of claiming the PTE for more than one patent on the basis of the same first marketing authorization. Pfizer Inc. is the owner of the Russian patent No. 2095358 (expired on August 12, 2014) protecting triazole derivatives, including 'voriconazole' (INN) and owner of the Russian patent No. 2114838 fully protecting voriconazole as a medicine for treating anti-fungal deceases (Vfend®) expiring on February 1, 2016. Both patents were extended, resulting in different expiration dates.

Canonpharma Production CJSC filed a nullity extension action against the Russian Patent Office, citing that the Russian patent No. 2114838 for voriconazole had been illegitimately extended since Pfizer Inc. had already extended the Russian patent No. 2095358 that also protected voriconazole. Subsequent extension of another voriconazole patent was therefore an abuse of right according to the plaintiff.

However, Canonpharma Production CJSC did not take into account that there was an issue of selective inventions. The first patent to the invention (2095358) relates to the Triazole derivatives, and is intended for "the use as antifungal agents for treating fungal infections in animals, including humans", while the second patent (2114838) is a pure selective invention which has enhanced properties when compared with the invention in the earlier patent. As it is follows from the second patent, the invention covered by the same also relates to Triazole derivatives exhibiting the antifungal activity but has an "unexpectedly high level of antifungal activity, particularly against fungal species Aspergillus spp., which is mainly attributed to their unexpectedly good pharmacokinetic properties, which are a consequence of the longer half-lives (values of t1/2)."

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According to the provisions in the Rules on the State Scientific and Technical Examination of Inventions (EZ-2-74):

> "When the new chemical compound (group, a variety of) has a structure related to a known group (a variety of chemical compounds, a positive effect shall either be new properties, which are not common for this variety, or of enhancing the properties known for this structure, or of other advantages (e.g., reducing toxicity, replacing deficient substances, etc.)".

That means that the second invention was patentable and the patent was granted legally[1].

Thus, both inventions related to the medicine for which the first marketing authorization was issued, since as it is follows from the structural formula of the substance Voriconazole with selected features of the invention, it relates to the invention as described in the independent claim of Patent No. 2095358, and to the invention disclosed in the independent claim of Patent No. 2114838.

On the basis of these circumstances the IP Court dismissed the nullity extension action, establishing that the two patents protect different inventions and the arguments of the applicant were recognized as aimed at challenging the novelty of the patents, which is subject to separate administrative proceedings in the PTO (later on, the Canonpharma Production CJSC's revocation action was dismissed by the PTO).

It should be noted that the above regulations and approaches are also applicable to the PTE procedures for Eurasian patents in respect of Russia. According to Rule 16 (5) of the Patent Regulations under the Eurasian Patent Convention, the period of validity of a Eurasian patent may be extended for a Contracting State whose legislation provides for the extension of the period of validity of a national patent. The period of validity of a Eurasian patent for such a Contracting State shall be extended by the Eurasian Office in accordance with the requirements and procedure envisaged by the legislation of this State for the extension of the period of validity of a national patent.

The practice of both Russian and Eurasian Patent Offices shows that the PTE procedure is actively used by patent owners, allowing them to extend the period of validity of their patents and gain a profit. This profit can then be further invested in researching new drugs, meeting the public interest and making the patent protection system well balanced.

[1] These were the Soviet rules regulating the work of examiners at the former USSR State Committee for Inventions and Discoveries. Those old Rules were used because they were valid at the time of filing the patent application.