GORODISSKY & PARTNERS

PATENT AND TRADEMARK ATTORNEYS

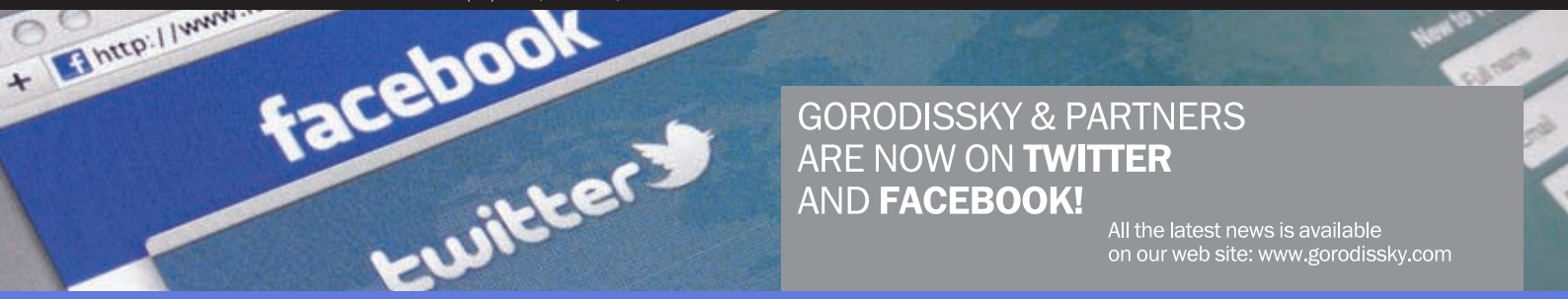
INFORMATION BULLETIN

GORODISSKY & PARTNERS

#78

IN THIS ISSUE:

#3 (78) 2011, MOSCOW, RUSSIA



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ELENA NAZINA, PARTNER, RUSSIAN AND EURASIAN PATENT ATTORNEY, GORODISSKY & PARTNERS (MOSCOW)

EXTENSION OF PATENTS FOR PHARMACEUTICALS AND AGROCHEMICALS

In Russia the procedure for extending the validity term of a patent for an invention relating to products which require a special marketing authorization, such as drugs, agrochemicals and pesticides, was firstly introduced in 2003.

At present, the procedure for patent term extension is defined by Article 1363 (2), Part IV of the Civil Code of the Russian Federation (CCRF), which states : "If from the filing date of an application for the grant of a patent for an invention directed to drug, pesticide, or agrochemical, the use of which requires duly granted authorization, and until the date of granting the first marketing authorization more than 5 years have elapsed, the validity term

of the exclusive right to the respective invention and the patent certifying this right shall be extended upon a request of the patent holder by the federal executive authority for intellectual property (the Russian PTO)". The procedure for patent term extension is regulated by Item 10 Part III of the Administrative Regulation for patent term extension (hereinafter the Regulation).

TERMS AND DOCUMENTS

In accordance with Article 1363(2) of the CCRF, a request for patent term extension shall be submitted within 6 months from the issue date of the first marketing authorization or the date of grant of a patent, depending on which expires later.

The request shall be submitted in the form set forth by Item 10.7 of the Regulation.

According to the procedure for patent term extension, a number of documents shall be provided proving the fact of obtaining the permission for use of the product and comprising information about the product structure/composition that allows one to assign the invention according to the patent to the product for which the marketing authorization is obtained.

As a document proving the fact of obtaining the marketing authorization, it is obligatory to provide a notarized copy of the first State Registration Certificate, wherein the registration date of the preparation is indicated, which is required for calculation of a possible patent term extension, and wherein either international nonpropriatory name (INN) of an active agent of the drug or its complete qualitative and quantitative composition is indicated.

Unfortunately, the Regulation does not clarify what the "first marketing authorization" is.

Our practice shows that the definition of the "first marketing authorization" does not necessary relate to the time of obtaining the permission.

That means if the patent relates to a compound per se, the first permission for request is undoubtedly a marketing authorization obtained first in time for a product comprising this compound as an active agent in any preparative form, and, if the substance is manufactured in Russia – an authorization for manufacture of the substance.

A slightly different situation is for patents relating to the products which are either some specific forms of an active agent (for example, crystalline forms, isomers, etc.) or preparative forms (for example, forms with a specific release profile of an active agent). In this case, the first marketing authorization for the product is not one issued first in time, but a first authorization which relates either to a product comprising an active agent in a specific form or to a specific preparative form of the product.

For example, the term of the Russian patent № 2214244 relating to a preparative form with sustained release, comprising an agent defined as a group of compounds of a general formula, was extended on the basis of the marketing authorization of July 31, 2009 for product Advagraf (immunodepressant) in the form of prolonged-release capsules comprising Tacrolimus (INN) as an active agent.

The term of the Russian patent № 2079303 relating to a drug in the form of an oinment comprising an agent defined as a group of compounds of a general formula, was extended on the basis of the marketing authorization of March 12, 2010 for product Protopic (immunosuppressive preparation) in the form of an ointment for external application comprising Tacrolimus (INN) as an active agent.

With that, none of above permissions was the first one for the substance Tacrolimus.

In addition to the above marketing authorization for the product, there shall be provided, as a rule, data about the structure of an active agent which is designated in the registration certificate by INN.

In this connection, it certainly should be noted that the Russian PTO has significantly indefinite requirements for such kind of documents. While within the first years after introducing this provision, it was necessary to provide the certified copy of the technical documentation for the drug submitted for registration procedure. At present it is allowed to submit data about the chemical structure of a compound having a registered INN, the structure being published in "WHO Drug Information" and the international reference book of "WHO International Nonproprietary names for Pharmaceutical Substance. Cumulative List". Furthermore, it is allowed the use of information from reference books such as, for example, Merck Index, as well as information from the documentation for the drug published on the official FDA website.

As a rule, the above documents are sufficient for obtaining a positive decision on the request for term extension of a patent relating to a compound per se.

However, if the matter is about a patent relating to a product which is characterized by some physical characteristics, for example, relating to the crystalline form of a known drug characterized by X-ray spectrum, or a preparative form characterized by a specific release profile of an active agent, the patent holder is obliged to submit evidences that the active agent of the drug is used exactly in the indicated specific crystalline form, or that the preparative form has a release profile of an active agent identical to that of the patented product. As a rule, the system of evidences in such a case is far more complicated and the set of documents differs.

Further, in addition to the above documents, in accordance with Item 10.9 of the Regulation, there shall be submitted an explanation regarding the claims. In particular, for every claim, a feature combination corresponding to the characteristics of the product shall be indicated.

IF FROM THE FILING DATE OF AN APPLICATION FOR THE GRANT OF A PATENT FOR AN INVENTION DIRECTED TO DRUG, PESTICIDE, OR AGROCHEMICAL, THE USE OF WHICH REQUIRES DULY GRANTED AUTHORIZATION, AND UNTIL THE DATE OF GRANTING THE FIRST MARKETING AUTHORIZATION MORE THAN 5 YEARS HAVE ELAPSED, THE VALIDITY TERM OF THE EXCLUSIVE RIGHT TO THE RESPECTIVE INVENTION AND THE PATENT CERTIFYING THIS RIGHT SHALL BE EXTENDED UPON A REQUEST OF THE PATENT HOLDER BY THE FEDERAL EXECUTIVE AUTHORITY FOR INTELLECTUAL PROPERTY (THE RUSSIAN PTO)

TERM OF EXTENSION

A possible patent term extension is calculated as a period from the filing date of an application (for an international application – the international filing date) to the date of obtaining the first marketing authorization minus 5 years.

Thus, a patent term extension is not provided for product-relating patents for which a permission for application has been obtained within 5 years from the filing date of the application for an invention.

The maximum patent term extension may not exceed a period of 5 years.

SELECTION OF A SUBJECT MATTER FOR TERM EXTENSION

In accordance with Items 10.5 and 10.6 of the Regulation, an invention relates to a drug, pesticide, or agricultural chemical, if the invention is characterized as a compound or a group of compounds of a general structural formula, or is characterized as a composition.

Thus, the national legislation limits a range of patents which are allowed for term extension, to patents relating to a product per se.
Indeed, the practice shows that, if a patent relates to a group of inventions inclining, for example, a compound, a pharmaceutical composition comprising the compound, a method for producing the compound, and a method for treating, the term of the patent will be extended only for claims relating to a compound and pharmaceutical composition.
Somewhat different situation is for claims relating to the subject matter "medical use".
In spite of the fact that the Regulation never mentions such subject matter in relation to drugs, in practice, claims relating to a medical use are included into the claims in relation to which the term of the patent is extended.
The term of the Russian patent №2260013, for example, was extended based on the marketing authorization for drug BRIDAN (selective antidote against myorelaxants) comprising Sugammadex (INN) as an active agent in the form of a solution for intravenous administration, in regard to, inter alia, claim 6 relating to a use of the compounds for therapy.
The term of the Russian patent №2114860 was extended based on the marketing authorization for ATRIANCE preparation (antitumor medicine) in the form of a solution for intravenous infusion comprising Nelarabine (INN) as an active agent, in regard to, inter alia, claims 11-13 relating to a use of the compounds for therapy.
Claims in relation to which the term of the patent is extended are maintained in their full scope, even if they do not relate to a single invention for which the marketing authorization is issued, but also to a group of inventions, for example, to a group of compounds defined by a general formula.

SELECTION OF THE PATENTS FOR THE TERM EXTENSION PROCEDURE

It is a common situation in practice where a patent holder has more than one valid patent relating to a registered product, for example, a patent for a compound per se, a patent for a pharmaceutical composition (in a general form), a patent for a drug, and a patent for a specific formulation.
Current legislation directed to the procedure of patent term extension does not have any provisions regulating such a case. Nor there is a prohibition against term extension for more than one patent on the basis of one marketing authorization for a product.
The absence of the prohibition against the term extension for more than one patent is also supported by the current practice.
For example, on the basis of the marketing authorization for drug ATRIANCE (solution for infusion) comprising Nelarabine (INN) as an active agent, the terms of two Russian patents were extended:
№2112765 relating to a pharmaceutical composition against Varicella zoster virus (VZV);
№2114860 relating to a group of compounds of a general formula and an antitumor pharmaceutical composition.
On the basis of the marketing authorization for drug Mimpara (film coated tablets) comprising Cinacalcet (INN) as an active agent, the terms of three Russian patents were extended:
№2146132 relating to a pharmaceutical composition showing an activity with respect to a calcium receptor;
№2147574 relating to a group of compounds of a general formula and a pharmaceutical composition showing an activity with respect to a calcium receptor;
№2195446 relating to a specific compound and a pharmaceutical composition modulating a calcium receptor activity.

DOCUMENT CERTIFYING PATENT TERM EXTENSION

Upon a positive decision on the basis of consideration of a request for patent term extension, an Enclosure to a patent is published. The Enclosure comprises an entry about the extension of the term of the exclusive right for the invention with indicating independent and dependent claims to which the term extension is applicable, and the date to which the term is extended.
Information about patent term extension are entered into the State Registry and published in the Official Bulletin of the Russian PTO.
As a conclusion, it is worth to note that an introduction of the provision relating to a patent term extension into the Russian national legislation and a majority of CIS countries is a significant positive step toward harmonization of the national patent legislations with international treaties, and more effective execution of rights of patent holders in the field of the pharmaceutics and agrochemicals. However, the procedure of a patent term extension in Russia and some CIS countries needs to be further improved, in particular, by addressing the most actual issues and amending and supplementing legislation regulating thereof.

CLAIMS IN RELATION TO WHICH THE TERM OF THE PATENT IS EXTENDED ARE MAINTAINED IN THEIR FULL SCOPE, EVEN IF THEY DO NOT RELATE TO A SINGLE INVENTION FOR WHICH THE MARKETING AUTHORIZATION IS ISSUED, BUT ALSO TO A GROUP OF INVENTIONS, FOR EXAMPLE, TO A GROUP OF COMPOUNDS DEFINED BY A GENERAL FORMULA.

NEWS

MAY 24-25.2011, MOSCOW
Vladimir Biriulin, Partner, "Gorodissky & Partners" (Moscow), gave a presentation "Management of intellectual property in the Customs union: combating piracy, counterfeiting and parallel imports" at the International forum "Customs Compliance in Russia and CIS". The issues of importation duty and costs minimization, border delays prevention and trade compliance operations optimization were discussed at the Forum which gathered lawyers practicing in customs law as well as the representatives of major international companies.

MAY 14-18, 2011, SAN-FRANCISCO

PHOTO: IP TEAM OF GORODISSKY & PARTNERS

A team of 11 IP lawyers and attorneys of "Gorodissky & Partners" from the Moscow and St. Petersburg offices attended the 133rd INTA Annual Meeting.
From May 15 to May 17 our clients and other participants of the conference visited the Gorodissky Hospitality Suite to discuss the latest amendments in the Russian IP legislation as well as their particular cases.
Gorodissky & Partners sponsored the nomination "Technology & Software Team of the Year" at the World Trademark Review Industry Awards 2011 Ceremony. The award went to Microsoft staff.
Over 800 guests attended the traditional Reception hosted by "Gorodissky & Partners" on May, 15.

APRIL 28, 2011, TYUMEN
Vladimir Mescheriakov, Counsel, Vladimir Bashkirov, Patent Agent (both of "Gorodissky & Partbers", Moscow, Sergey Egorov, Partner, Ekaterina Solonitsyna, Lawyer, Alexander Deryabin, Patent Agent (all of "Gorodissky & Partners", Ekaterinburg) gave presentations at the seminar "Topical issues of legal protection of inventions in Russia". The seminar was held by "Gorodissky & Partners" with Tyumen Regional Duma (Parliament), Tymen regional counsel of All-Russian Society of Inventors and Innovators and the Urals territory customs and gathered 40 specialists, among which are lawyers, patent experts and inventors.

APRIL 27, 2011, MOSCOW
Yuri Kuznetsov, Partner, Russian and Eurasian patent attorney, "Gorodissky & Partners" (Moscow), gave a presentation "Eurasian patent system – attorney's perspective" at the Conference "Patent – EurAsia 2011" held by the Counsel of Eurasian Patent Attorneys in Moscow State University. The advantages of the Eurasian Convention on the territories of member states were discussed at the conference which gathered more than 100 scientists, businessmen, inventors, Russian and Eurasian patent attorneys.

APRIL 20-22, 2011, MOSCOW

PHOTO: GORODISSKY'S SPEAKERS (FROM LEFT TO RIGHT) E.ALEXANDROV, V.BIRIULIN, N.STEPANOVA AND A.BOGACHEVA

The 9th Annual IP Seminar "IP Protection Strategy For Company's Successful Development" was held in the Moscow office of Gorodissky & Partners. Leading patent and trademark attorneys and lawyers from the Moscow, St.Petersburg and Kazan offices of the firm gave speeches on effective legal protection and management of a company's intellectual property in Russia and abroad, in the USA in particular. They shared with the most interesting and successful cases, new ways of IP disposal.
A Workshop on domain names was also in the seminar program.
Special guest - Mr. Yakov Korkhin, Principal of Scitech Legal (USA) gave a presentation "Balanced patent portfolio development strategy as a major determinant of company valuation".
At the Seminar there were 43 attendees from the state industrial companies, commercial firms, R & D centers, educational institutes, offices of foreign companies as well as patent attorneys and lawyers from Russia, Belarus and Kirgizstan.

APRIL 14, 2011, MOSCOW
Dr. Tatyana Pogrebinskaya, Counsel, Trademark Attorney, "Gorodissky & Partners" (Moscow), took part in the meeting of the Working group on intellectual property of Expert Counsel on customs regulation of the Russian State Duma (Parliament). Proposals on the Concept of the international agreement aimed at resolving current situation with trademarks of the former USSR caused by the formation of the Customs Union "Russia-Belarus-Kazakhstan" were discussed at the meeting. The change of the national principle of trademark rights exhaustion to the regional one in connection with the Agreement on uniform regulation principles in the field of IPRs protection to come into effect as of January 1, 2012 was also discussed.

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