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Legal Protection of Selection Inventions in Russia

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Last year the discussion on patenting of inventions in the pharmaceutical field unexpectedly was given a new start. The Federal Anti-Monopoly Service (FAS) poured oil on the fire of this debate, according to which the Russian PTO improperly allows granting patents for such "minor," from the point of view of FAS, improvements like the use of known pharmaceutical compositions for new purposes, new methods of treating diseases with the known pharmaceutical compositions and new methods of preparation of the known substances. According to FAS the issuance of these patents is abuse of intellectual property rights and reveals drawbacks in the procedure for granting patents.

In this connection, FAS proposed to exclude the possibility of patenting known substances, methods of treatment and methods of using the pharmaceutical compositions for a new purpose, which do not have any features of the invention, since the existence of such possibility leads, according to FAS, to multiple patenting of the same invention and the unreasonable extension the term of protection of intellectual property rights (FAS, following some patent agents, calls this technique the maintenance of an "evergreen patent").

Of course, the Russian PTO did not agree with this assessment of FAS of the situation in the field of patent protection of pharmaceutical inventions. The position of the Russian PTO is, that regardless of what a claimed invention represents (including the use for a new purpose, a new method of treatment with the known means, etc.), the base to provide legal protection is conformance to the requisites of patentability "novelty," "inventive step," and "industrial applicability." The Russian PTO noted that legal protection of inventions in the form of the use of a known substance for a new purpose and the method of treatment using a known substance, contrary to FAS, does not extend legal protection of the existing active ingredient. For example, » page 2

the current legislation allows obtain a patent for the use of the active substance for a new purpose. Furthermore, the validity of such a patent in no way shall be related to the life of the patent for the active ingredient. The issuance of such patents is the usual practice adopted in most developed countries, relying, inter alia, on international agreements.

The case in point went through all the judicial instances and the judgment of the Commercial Court of Moscow was upheld

It is generally acceptable throughout the world the issuance of patents for so-called "selection inventions," which, according to the opponents of such patents, also relate to "evergreen" patents. A selection invention is an invention related to a chemical compound falling within the general structural formula of the group of known compounds (the Markush formula), but not described as specifically obtained and investigated, and at the same time characterized by new properties unknown for this group in qualitative or quantitative terms. The selection inventions relate to chemical compounds, and the examination of applications is carried out in exactly the same way as the examination of patent applications for inventions relating to chemical compounds.

Assessment of the novelty of the claimed chemical compound is carried out according to the entire combination of its characterizing features (structure, presence of specific substituents in certain positions and mutual alignment of the groups and atoms within the molecule). With regard to the selection inventions, this assessment shall also be carried out without fail, and it precedes the analysis and accounting of the new property of the claimed chemical compound (novel in relation to the properties of the well-known group of chemical compounds described by the Markush formula). The record of this novel property, belonging to the technical result, is only one of the associated requisites for recognition of the patentability of a chemical compound itself, but it is not the unique and self-sustainable.

In Russia the problem in question is regulated by patent rules according to which: "a chemical compound falling within the general structural formula of a group of known compounds or a composition based on it are recognized as complying with novelty criteria if the chemical compound as such is not known from the prior art and there is no information regarding the basic substance, the process for its preparation and its properties, which became publicly available before the priority of the invention" (Para. 70 of the Rules for inventions of the Russian PTO).

Similarly, the procedure for checking compliance with the inventive level criteria of selection inventions is generally the same the procedure for checking the inventive level of other chemical compounds with the defined structure, i.e. account is taken of the difference in the properties of the claimed and disclosed compounds unified by a known formula of a common structure and the extent of this difference is taken into account (it is not considered being sufficient proof of an inventive level the difference between quantitative indicators within the margin of error) (paragraph 9.1.12. of the Examination Guidelines of Applications for Inventions). Accordingly, paragraph 78 of the Rules for inventions provides that a selection invention, i.e. a chemical mixture falling under the general structural formula of the group of known compounds, but not specifically described as specially obtained and studied, and at the same time showing new unknown properties in this group in qualitative or quantitative terms (selection invention), is recognized being non-obvious to a person skilled in the art and involves an inventive step requisite. Thus the patentability of inventions, called selection inventions, is based, like any other inventions, upon their statutory criteria. No case has come to our notice, in which the Russian PTO or the court would recognize the invention being patentable only because they qualified it as a "selection invention" without evaluating all of the criteria of patentability (novelty, inventive level and industrial applicability).

A spectacular example of a selection invention is the invention according to the Russian patent No.2114838 for a group of inventions "Triazole Derivatives, Pharmaceutical Compositions and Intermediates" issued in the name of Pfizer Inc. (US). The said patent, in particular, protects also the exclusive rights to the active substance having the international non-proprietary name (INN) of VORICONAZOLE. The invention characterized in independent claim 1 according to Russian patent No.2114838 relates to triazole derivatives of general formula I.

The compounds which are characterized by structural formula I in the independent claim 1 of the Russian patent No.2114838 are covered by the general structural form of a group of compounds known from the Russian patent No.2095358 (independent claim 1 and dependent claims 2, 3) as well as compounds which methods of preparation are known from the SU patent No.1836366 issued in the name of Pfizer Inc. (US). However, the compounds characterized by structural formula I under the Russian patent No.2114838 are not disclosed in the patent documents RF No. 2095358 and SU No.1836366, as specially obtained and studied. Thereby, in the specification of the invention under the Russian patent No.2114838 there are indicated the methods of preparing the compounds characterized in independent claim 1 and dependent claims 2-10. Furthermore, the specification contains experimental data evidencing that the compounds substituted by halogen in a certain position (substitute Y in the structural formula of independent claim 1), possess a surprisingly high level of antifungal activity (against species Aspergillus spp fungi) in comparison with the compounds disclosed under the Russian patent No.2095358 but which do not have the above-mentioned substitute. Thus, the triazole derivatives of the general formula I according to independent claim 1 under the Russian patent No.2114838 exhibits quantitatively new properties comparing with the compounds described in patent documents RF No.2095358 and SU No.1836366 as specially obtained and studied. It is conducting special research and discovery of new properties that allowed Pfizer Inc. (US) obtain the said patent for the selection invention.

Meanwhile, other pharmaceutical market players - producers of generics are not comfortable with such approach. They believe that patents for selection inventions should not be issued because they artificially extend the term of validity of the earlier patent for a group of compounds covered by the general structural formula of the group of compounds contained in the original patent with an earlier priority date.

In particular, this became one of the key issues in case No.A40-30012/2015, which was considered by the Moscow Commercial Court.

In the case in question Pfizer Inc., (US) filed a lawsuit against the CJSC Canonfarma Production and its distributors for protection of the exclusive rights for the invention under the patent No.2114838 which protects the active ingredient INN VORICONAZOLE. The respondent for its part argued that since the active ingredient VORICONAZOLE is covered by the general structural formula of the patent No.2095358 which term of validity has expired, hence marketing of the pharmaceutical composition with the active ingredient INN VORICONAZOLE does not violate the patent No.2114838 since the invention passed into the public domain in accordance with Art. 1364 of the Civil Code of the Russian Federation. In order to verify the parties' submissions the court ordered an expert report. In their report the experts confirmed that the controversial pharmaceutical composition both the invention under the patent No.2114838 and the invention under the patent No.2095358 are used. Having analyzed the expert opinion the court stated that the conclusion of experts on the use of the invention under the Russian patent No.2095358 does not repeal and in no way affects the conclusions of the experts on the use of the invention under the Russian patent No.2114838. Without regard to the number of patents used in the pharmaceutical composition the conclusion on the use of the particular patent remains unchanged. The simultaneous use in the pharmaceutical composition both of the patent which has passed into the public domain, and the patent being in force, is not a ground for discharging of responsibility for infringement of the exclusive rights to the patent being in force.

The law contains no ban on the use in the pharmaceutical composition of more than one patent; however, the law bans the use in the pharmaceutical composition of a patent without the consent of the patent owner (Articles 1229, 1358 of the Civil Code of the Russian Federation). That is why the use in the pharmaceutical composition "Voriconazole Canon" according to the Russian patent No.2095358 (passed into the public domain due to expiration of the period of validity) does not make lawful the use in the same pharmaceutical composition according to Russian patent No.2114838 being in force. A different interpretation would purport the open-ended opportunity to avoid liability for violation of intellectual property rights through the simultaneous use of both the invention passed into the public domain and the invention under the patent being in force. Neither Article 1229 of the Russian Civil Code, nor Articles 1358 or 1359 of the Civil Code contain such an exception / ground for exemption from liability for infringement of the exclusive rights in the invention. The conclusion about the use of the invention under the Russian patent No.2095358 which passed into the public domain in accordance with Article 1358 of the Russian Civil Code does not negate the inference about the use of the valid Russian patent No.2114838, for infringement of the exclusive right to which the liability is incurred in accordance with Article 1252 of the Civil Code.

The Russian patents Nos.2095358 and 2114838 protect different technical solutions, "otherwise these patents could not have been issued." Aside from the above arguments the respondent argued that the company Pfizer Inc. abused its right by extending the life of the patents of the Russian Federation Nos.2114838 and 2095358, since by its actions the company tried to limit competition and occupy a dominant position on the market of pharmaceuticals.

Meanwhile the Court for intellectual property rights noted in its decision that according to the tenor of paragraphs 1 and 2 of Article 10 of the Civil Code for recognition of actions of a person as the abuse of the right the court should establish that the malice of such a person was directed to a willful unfair use of the rights; that his or her only goal was causing harm to another person (the absence of other bona fide purposes). This abuse of right must have sufficiently clear character and the conclusion to that effect should not be the result of speculation. However Canonfarma Production did not provide relevant evidence in the case file. At the same time, on their own right, the actions of Pfizer Inc. to extend the period of validity of the aforementioned patents did not contradict current legislation.

As a result of consideration of this dispute the court found the patent for the selective invention being infringed. Thereby, in fact, the Court confirmed that the patent for the selection invention is subject to protection regardless of the term of validity of the original patent having the general structural formula of a group of compounds which the selection invention falls under. Furthermore, the court confirmed the right of the patent owner to renew both patents (the original patent and the patent for the selection invention) on the basis of the same marketing authorization according to the provisions of paragraph 2 of Article 1363 of the Russian Civil Code.

The case in point went through all the judicial instances and the judgment of the Commercial Court of Moscow was upheld.

As it was mentioned in this article, the issue of the long-term validity of patents for pharmaceutical compositions including patents for selection inventions, worries both the manufacturers of generics and the FAS. The Federal Anti-Monopoly Service expresses extreme concern over a possible monopoly on the invention in such a vital area as pharmaceuticals and believes that the law favors artificial extension of validity of a patent in the pharmaceutical field.

FAS has drafted several versions of changes in the Civil Code of the Russian Federation aimed at allowing the use of patented inventions without the consent from the patent owner (through a compulsory licensing mechanism or issuing a use permit by the Government).

In one of the legislative drafts in particular, it seeks to complement Article 1350 of the Civil Code with a provision regarding the right of the government to allow the use of an invention, utility model or industrial design without the consent of the patent holder in order to protect the life and health of the people. Now the law allows the government to do so in the best interests of defense and security. In any case, both the current legislation and the legislative draft provide that the right holder shall immediately be notified of such a government decision and it should be paid commensurate compensation.

Until now, all FAS initiatives to amend the legislation in this regard have been rejected by the government, and all the patents issued within the framework of existing legislation continue to have effect and are subject to protection by the state. As the heads of the Russian PTO correctly pointed out at the roundtable discussion organized by the Office in February 2016 any decisions related to the change in the pharmaceutical patenting practice should be well balanced and coordinated with all interested parties.

The current legislation allows obtain a patent for the use of the active substance for a new purpose

Events (conferences, seminars, news)

NEW PARTNERS AT GORODISSKY & PARTNERS
24.02.2017 // MOSCOW

Photo: (from left to right) Alexander Mits, Viacheslav Rybchak, Sergey Abubakirov, Vadim Bloshentsev

Partnership of "Gorodissky & Partners" is glad to announce that Alexander Mits, Russian & Eurasian patent Attorney, Head of Filing department, Moscow office. Viacheslav Rybchak, Trademark & Design Attorney, Trademark department, Moscow office Sergey Abubakirov, Russian & Eurasian Patent Attorney, Head of Annuities Department, Moscow office.
Vadim Bloshentsev, Trademark Attorney, Director, Krasnodar branch office have become partners of the firm.

7.02.2017 // MOSCOW

Valery Narezhny, PhD, Counsel (Gorodissky & Partners, Moscow), spoke on "Tax arrears recovery from the debtor`s interdependent and affiliated persons" at the Seminar "Recovery of damages from the management of a legal body, controllers` responsibility in bankruptcy" held by the Moscow Chamber of Commerce and Industry (MCCI) in Moscow.

Photo: Valery Narezhny (at the far right)

8.02.2017 // KRASNODAR

Vadim Bloshentsev, Partner, Trademark Attorney, Regional Director (Gorodissky & Partners, Krasnodar), spoke on "IP in innovative agro-business" at the track program "AgroBioTech&Food" held by a federal technology start-up accelerator "GenerationS" in Krasnodar.

9.02.2017 // VLADIVOSTOK

Photo: (from left to right) Vladimir Biriulin, Nikolay Ptitsyn

Vladimir Biriulin, Partner, Russian Patent Attorney (Gorodissky & Partners, Moscow), and Nikolay Ptitsyn, Attorney at Law, Trademark Attorney (Gorodissky & Partners, Vladivostok), spoke on "Intellectual property and ways to register your IP rights", "Civil liability for IP rights infringement", "Intellectual property and business development" and "Administrative responsibility and prosecution for IP rights infringement" at the 1st Seminar "IP in modern business" held by Gorodissky & Partners in cooperation with the Business Development Centre in Vladivostok.

10.02.2017 // MOSCOW

Valery Medvedev, Managing Partner, Russian & Eurasian Patent Attorney, Yury Kuznetsov, Partner, Head of Patent Practice, Russian & Eurasian Patent Attorney and Vladimir Trey, Partner, Trademark Attorney (all of Gorodissky & Partners, Moscow), participated in the Open briefing of the General Director of the Russian PTO Gregory Ivliev held by AEB in Moscow. Mr. Ivliev focused on the Russian PTO's activity and plans for further development of IP law in Russia.

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