AIPLA
American Intellectual Property Law Association

Chemical Practice Chronicles

Newsletter of the AIPLA Chemical Practice Committee

Fall 2023 Volume 11 Issue 1

Articles

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Fighting Against Patent Evergreening Can Help Originator Companies in Russia

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I. Introduction

When patents for chemical subject matter, it may be desirable to not only patent a compound, but also its derivatives, such as salts and polymorphs thereof. Patent law relating to pharmaceuticals is continually changing in Russia in order to achieve an optimal balance between the rights of patent holders and the needs of society, and between the rights or interests of originator companies and that of generic drug makers. This article discusses recent legal developments in Russia concerning the patenting of new derivatives of known substances.

II. Background of patenting chemical compounds

In Russia, patents can have claims to a chemical formula that represents a group or class of chemical compounds rather than a single compound ("Markush structure"). A Markush structure includes a generic part that defines the common structural element of related chemical compounds and specific parts that identify individual compounds falling under the generic formula. The specific parts include variable groups that can be interchanged without affecting the generic formula. Patent claims can also relate to a specific compound. Regardless of whether patent claims relate to a group of compounds or a specific compound, the claims may define derivatives of the compound(s), e.g. pharmaceutically acceptable salts, esters, or stereoisomers. To protect derivatives, applicants have to show, by means of examples in the original specification or submitted additionally, the preparation and activity of the derivatives in addition to those of the claimed compounds in their free form. Sometimes, examiners of the Russian Patent and Trademark Office (Rospatent) will accept an argument that pharmaceutically acceptable salts of biologically active compounds can be expected to have the same biological activity as the claimed compounds in free form and that the preparation of said salts is a routine matter and within the skill of the ordinary skilled person. In such event, an applicant can avoid submitting additional examples illustrating the preparation and characterization of the salts.

However, the situation is different when an applicant is seeking to obtain a secondary patent for a new derivative of a compound that has already been patented. A secondary patent refers to a patent granted for an improvement or modification of an existing chemical compound, which has already been protected by a primary patent.

Secondary patents have been criticized for "patent evergreening." Patent evergreening refers to a strategy of obtaining additional patents for a drug that has already been patented by claiming different aspects of the same drug or minor modifications thereto. The additional patents can have patent terms that extend beyond the term of the original patent thereby preventing or delaying market entry of lower cost generic equivalents and limiting patient access to affordable

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medicines, particularly in developing countries where high drug prices can be a barrier to treatment.

III. Attempts to Fight Against Evergreening

According to the experts from Skolkovo Innovation Center, more than 70% of pharmaceutical patents granted in Russia are secondary patents [2]. Attempts have been made to prevent patent evergreening [1].

These attempts include reducing opportunities to patent prior patented compositions in a secondary patent [1]. Thus, on October 1, 2018, the Ministry of Economic Development of Russia issued an act on amending the Guidelines for drafting, filing and examining documents for the state registration of inventions (clauses 70 and 76) and the Requirements imposed on the documents of patent applications (clauses 39.3 and 53.14). The amendments came into effect on December 15, 2018. In accordance with said amendments, a composition cannot be described by:
- information that is not directly related to the composition (for example, conditions and regimes of use of the composition in a process or a method);
- a quantitative parameter (measured or calculated) that defines one or more characteristics of the composition (for example, lamination strength, cracking resistance, pharmacokinetic profile, etc), if this parameter is used as an essential feature in an independent claim;
- a technical result achieved by production or use of the composition.
The introduced provisions also restricted patenting of pharmaceutical compositions: pharma compositions cannot be described by features related to methods of treatment (e.g., dosage regime, administration schedule of the compositions or drugs based on the compositions). The above features if included in the claims will not be considered in the assessment of the compliance of invention with the novelty and inventive step criteria.

Further, the Ministry of Economic Development of the Russian Federation issued Order No 155 which came into effect on June 08, 2021 that supplemented clause 77 of the Russian Patent Rules whereby, to be deemed inventive, a new form or derivative of a known compound (e.g., an isomer, stereoisomer, enantiomer, amorphous or crystalline form, a salt, solvate, hydrate, complex compound, or an ether/ester) must exhibit novel properties in qualitative or quantitative terms in comparison with the known compound, which properties are non-obvious to the skilled person based on the prior art.

In addition, the Order supplemented clause 47 of the Patent Requirements to explicitly require reliable data to be submitted, which data shall support novel properties of a claimed new form or derivative of a known compound in qualitative or quantitative terms in comparison with the known compound that are non-obvious to a skilled person based on the prior art. If a claimed form or derivative exhibits a biological activity which is useful for preventing, treating, or diagnosing a disease, corresponding data obtained in an appropriate model shall also be submitted.

The above-mentioned novel properties are considered a technical result, i.e. a beneficial technical effect provided by the invention. Under Russian law, a technical result and the

achievement thereof are taken into account when sufficiency of disclosure and inventive step are assessed.

Since the coming into force of the Order in mid-2021, Rospatent examiners have been rejecting new forms or derivative of known compounds for lacking inventive step, despite there being shown new technical effects, such as increased stability of a polymorph, increased efficacy of one isomer or enantiomer in comparison with another. Thus, presently, additional efforts may be required to prove non-obviousness of novel forms or derivatives of known compounds. For example, it is recommended to submit comparative data showing that not all forms or derivatives can achieve the established technical result. In addition, applicants should be ready to provide detailed technical comments to explain why a skilled person could not have expected the technical result achieved by the claimed new form or derivative.

IV. The Impact of the Order on Pharmaceutical Companies

Russian patent attorneys and lawyers have different opinions on the effect of the Order. Some specialists consider that the amendments introduced by the Order change nothing in principle; that is, the Order did not prohibit the subsequent patenting of new forms and derivatives, but simply made already existing requirements for patenting secondary inventions statutory. Other specialists consider that the amendments introduced by the Order may affect the rights of originator companies and stifle innovation in Russia.

That said, the amendments may affect the rights of generic drug companies as well to the extent that they make it more difficult for a generic drug company to obtain patents to a dependent invention. See Article 1358.1 of the Russian Civil Code which stipulates that:

> "*1. An invention, utility model, industrial design, the use of which in a product or method is impossible without the use of another invention, another utility model or another industrial design protected by a patent and having an earlier priority, are the dependent invention, dependent utility model, dependent industrial design, respectively.*
> …
> *2. An invention, utility model or industrial design may not be used without the permission of the owner of a patent for another invention, utility model or industrial design, in relation to which they are dependent*".

Further, Article 1362(2) of the Russian Civil Code gives the owner of a patent for a dependent invention the right to require a compulsory license to a patent on a "main" invention, via court proceedings.[46] Sometimes, this strategy is used as a defence to infringement of the "main" patent.

[46] Since 2018, Nativa, a Russian pharmaceutical company, has commenced court proceedings seeking a compulsory licence to patents owned by international originator companies such as Celgene, Novartis, AstraZeneca, etc. The basis of such lawsuits was Nativa's patents on derivatives of biologically active compounds that were developed and patented by the originator companies [1]. Nevertheless, as of the end of 2022, no compulsory licenses were granted by the court to Nativa. Almost all lawsuits were rejected or terminated because either Nativa's corresponding patents were revoked, or Nativa and the originators reached settlement agreements.

Thus, the greater difficulty in obtaining secondary (dependent) patents due to Order No 155 also impacts rights of generic drug companies by limiting their ability to seek compulsory licences to main patents owned by originators.

V. Summary

Order No 155, which came into effect on June 08, 2021, amended Russian patent law to expressly require evidence probative of inventive step which arguably renders it more difficult to secure patents to secondary (dependent) inventions. Consequently, the Order can be seen to balance the interests of originator companies and generic drug makers by impacting their interests equally, and also to promote the interests of society by combatting evergreening.

VI. References

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