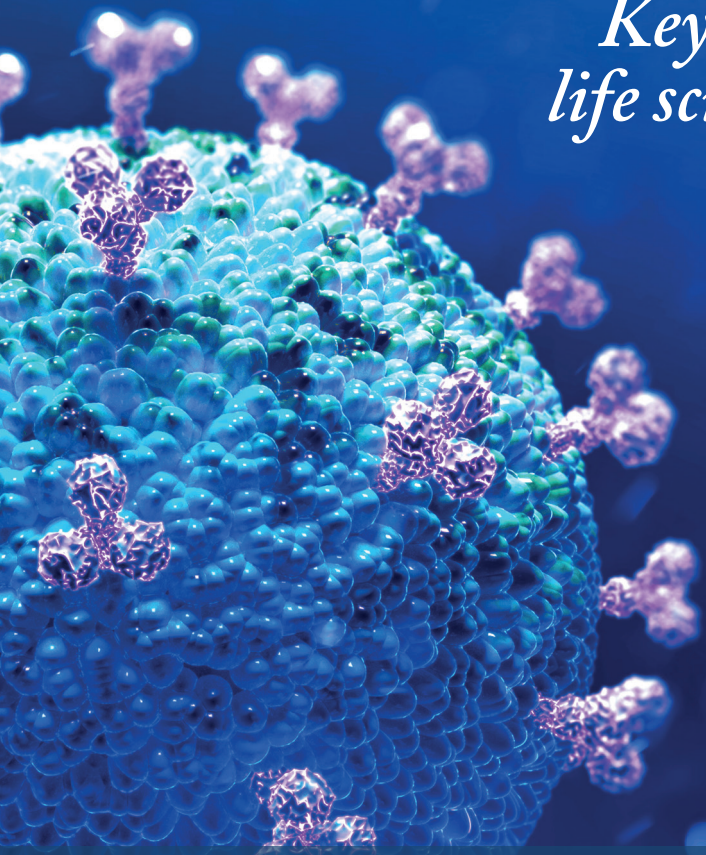
Life Sciences 2020

Key issues for senior life sciences executives



Second medical use inventions – Russian and Eurasian patent legislation

Gorodissky & Partners

Lev Zhilin

iam®

Gorodissky & Partners

Practicing since 1959

PATENTS, TRADE MARKS, DESIGNS
UTILITY MODELS, COPYRIGHTS
LITIGATION, IP DUE DILIGENCE
ANTI-COUNTERFEITING, MEDIATION, LICENSES, SEARCHES
TRANSLATIONS

Moscow, St. Petersburg
Kazan, Ekaterinburg
N.Novgorod, Krasnodar
Vladivostok, Samara
Novosibirsk, Perm
Sarov, Dubna, Ufa, Kiev

GORODISSKY

Head Office:
B. Spasskaya Str., 25, bldg. 3
Moscow 129090, Russia
Tel.: +7(495) 937 6116
Fax: +7(495) 937 6104/6123
E-mail: pat@gorodissky.com
www.gorodissky.com

Second medical use inventions – Russian and Eurasian patent legislation

By Lev Zhilin

When patenting inventions in Russia, one potential route is granting a patent for an invention relating to a well-known product used for a new purpose, the so-called 'second medical use invention'.

National and regional patent systems

There are currently two patent systems in Russia – the national patent system represented by Rospatent, and the regional patent system represented by the Eurasian Patent Office (EAPO). A patent for a new medical use of a known product can be granted by filing an application with either Rospatent or the EAPO.

Rospatent requirements

The patent law in force in Russia until mid-2016 allowed for the protection of inventions aimed at a product whose distinguishing feature was a new, previously unknown medical purpose. The format of claims relating to such products was: "a pharmaceutical composition/formulation/combination/dosage form/kit, etc, for treating disease Y comprising known compound/substance X".

At the same time, despite the product's availability, the new purpose of 'treating disease Y' makes it possible to recognise the novelty of the proposed invention. Until mid-2016, a new medical use of a well-known product could be patented in Russia both in the format of a claim characterising the product with the indication of its new intended purpose (eg, in the form of a drug, composition or dosage form, or in the form of use of said product for a new intended purpose and a method of treating a disease using said product). However, after new patent filing rules and documentary requirements entered into force in Russia in July 2016, a new medical intended purpose as the only distinguishing feature for a product was excluded.

In accordance with Article 70 of the rules (as amended 1 October 2018): "if the difference in the generic concept is caused only by the properties objectively inherent in the claimed product, including previously unknown properties, the claimed product is not recognised as novel. In this case, the applicant has the right to characterise the claimed invention in the claims in the form of the use of the product for a specific purpose specified in the generic term."

Therefore, it is assumed that a new previously unknown purpose of a known product – even if caused by new previously unknown properties of the product discovered by the applicant – is recognised as being inherent in the known product, meaning that the product does not meet the patentability condition of novelty. The applicant is invited to reword a claim so that it relates to the use of a known product for a new intended purpose.

After Rospatent adopted the new rules and requirements, the possibility of protecting a new medical use of a product in the 'product for treatment' format was excluded from Russia's legislation. In this regard, the protection of a new medical use of a known product became possible only as a 'subject matter', such as use of the product for a new intended purpose or a method of treatment using the product for a new intended purpose.

'Use for treatment' subject matter

Second medical use as an invention is defined in Article 1350 of the Civil Code: "As an invention, a technical solution is protected in any field that relates to a product (in particular, a device, substance, strain of a microorganism, a plant or animal cell culture) or a method (a process of carrying out actions in respect of a material object by material means), including to use of the product or method for a specified purpose."

In Clause 53(22) of the requirements (August 2016), an invention relating to the second medical use is additionally defined as "for the invention, characterised in the form of its use for a specific purpose, a claim has the following structure: Use … (the name or characteristic of the product or method is given) as … (the purpose of the specified product or method is given)".

The essential features that are sufficient to characterise this subject matter are the characteristics of the product and its intended purpose. The indication of other additional features such as dosage, administration route and regimen are admissible; however, such an indication will be considered by the examiner as evidence that the invention is not just a new use of the product, but rather a new method of dosage or administration to achieve the indicated intended purpose, in view of additional restrictions caused by the indicated features, and protected in accordance with Russian legislation as a method of treatment.

According to current practice, a product for which a new use has been identified may relate to a compound for which the new use has been identified, and to a product (eg, composition, combination or dosage) containing this compound.

The following formats of the claims characterising an invention relating to use for a new medical purpose are admissible:

- use of substance X for treating disease Y;
- use of a composition, formulation or dosage, among others, containing substance X for treating disease Y; and
- use of substance X for manufacturing a medicine for treating disease Y.

In accordance with Article 1358(2) of the Civil Code, "the use of an invention, and, accordingly, infringement of a patent, shall be considered, in particular: import into the territory of the Russian Federation, manufacturing, exploitation, offer for sale, sale, other introduction into civil circulation or the storage for such purposes of a product … intended for its use in accordance with the purpose specified in the claims, while protecting the invention in the form of use of a product for a specific purpose."

The scope of exclusive rights of a patent containing claims for "use a product for a specific purpose" applies directly to the product used for the specific purpose, but not only its use for this purpose. However, it is necessary to consider the practice established in Russia, according to which the indication of features relating to a method of treatment, in the claim for use of a product (namely, the indication of dose and regimen of administration of a medicinal substance) will lead to the claim being considered as related to "a method of treatment".

'Method of treatment' subject matter

According to patent legislation, a new medical use of a known product can also be protected as part of a method of treatment. In accordance with Clause 43 of the requirements, methods are characterised using, in particular, certain features. Unlike the 'use' subject matter, the 'method of treatment' subject matter is characterised by additional features relating to a certain order of actions on a product, conditions or modes, among others, which specifies the subject matter and, thereby, limits the scope of exclusive rights to a patent.

However, if an invention is directed to a new medical use of a known product, the claim relating to a method of treatment can be drafted without inclusion of the above features and, similarly, the claim relating to use may contain only the characteristic of the product and its new purpose,

"A product for which a new use has been identified may relate to a compound for which the new use has been identified, and to a product containing this compound"

"A claim should start with the name of the object reflecting its intended purpose"

usually indicating that the product is administered in a therapeutically effective amount. For example, the claim may be worded as follows: "a method for the treatment of Y, comprising administering X in the therapeutically effective amount". However, even with this characteristic of the subject matter, it should be kept in mind that the scope of exclusive rights will not correspond to the scope of exclusive rights of a patent relating to "use of X for the treatment of Y/manufacture of a medicine for the treatment of Y" since, in this case, the violation will be established when confirming the use of all the features of the method, including the administering feature.

Eurasian Patent Convention requirements

According to the Eurasian legislation, the features by which a subject matter such as 'composition' can be characterised pursuant to the requirements of Clause 2.5.4.4, include:

- qualitative composition (ingredients);
- quantitative composition (content of ingredients); and
- structural characteristics.

In addition, in accordance with Article 2.6.2 of the rules, a claim should start with the name of the object reflecting its intended purpose. Moreover, the rules also specify the mandatory features of a composition as a subject matter, which, pursuant to Article 2.6.7, are defined as "the features characterising the ingredients included therein and, if necessary, the features characterising their quantitative content, expressed in any units, as a rule, by two values defining the minimum and maximum limits of the content".

The purpose is not included in the list of mandatory features by which a composition will be characterised; however, in practice, the EAPO examiners require that the purpose be specified for the composition subject matter, based on the requirement of Clause 2.6.2. In addition, in the assessment of the patentability of a subject matter such as composition, a new purpose is not taken into account since, in light of Clause 2.5.4.4 and Clause 2.6.7, the new purpose is not considered as the feature characterising the 'composition'.

So, as with Russian patent law, in accordance with the requirements of the Eurasian Patent Law, a well-known product that has the only distinguishing feature characterising a new purpose cannot be protected in the 'product X for treatment of Y' format. Protection of such a product – taking into account the requirements of the EAPO

Lev Zhilin
Russian and Eurasian patent attorney
zhilinl@gorodissky.com

Lev Zhilin graduated from the People's Friendship University of Russia in 2005. Until 2007 he worked as a patent expert for Rospatent. Since 2007 he has worked for Gorodissky & Partners, where he deals with the representation of Russian and foreign pharmaceuticals, food, cosmetics and chemical companies, and advises on patent strategy in Russia and Eurasia. Mr Zhilin's areas of particular experience include biologically active substances (eg, drugs, veterinary drugs, detergents, disinfectants, cosmetics and perfumes) and their use; targeted medical products and diagnostic measures; treatment, prevention and diagnosis methods. He represents clients before Rospatent and the Eurasian Patent Office in objection cases against patent grants.

"The 'use' subject matter, according to Eurasian legislation, is characterised by the same features as a similar subject matter according to Russian legislation, that is, by characterisation of a product and its new purpose"

legislation – is possible in only two formats: "use of this product for treatment" and "a method of treatment using said product".

Use

The 'use' subject matter is defined in Subclause 1.1 of the rules. The subject matter of the invention is the "use of a device, method, substance, biotechnological product". The use of a device, method, substance or biotechnological product means use for an unknown purpose.

In accordance with Clause 2.5.4.8, the 'use' subject matter can be characterised as "the use of a device, method, substance, biotechnological product, including for the first purpose, is characterised by characterisation of an object used, sufficient for the identification of this object, and by indication of this first purpose".

Therefore, the 'use' subject matter, according to Eurasian legislation, is characterised by the same features as a similar subject matter according to Russian legislation, that is, by characterisation of a product and its new purpose. The claims relating to use but containing features such as regimen and method of administration and dosage are not allowed, since it is assumed that they characterise a subject matter such as method of treatment, rather than a new medical use of the product.

Method of treatment

According to Section 2.5.4.2 of the rules, the features used to characterise the method (in general, not only a method of treatment) are the following:

- performed actions (operations);
- sequence of actions (operations);
- conditions for performing actions (operations); and
- the use of substances (eg, raw materials, reagents and catalysts), devices, strains and modes of operation.

This is supplemented with the requirements of Clause 2.6.6 of the rules, according to which the features of the method subject matter are: "features that reflect the presence of actions or operations, the combination of which provides the implementation of the method, the sequence of the actions or operations, conditions and modes for performing them, as well as means, use of which the method is implemented (raw materials, reagents, devices)". The features that characterise directly the method of treatment are those that indicate a specific dosage regimen of a product, conditions or regimens of its administration.

Similar to Russian legislation, a subject matter (eg, a method of treatment) can be used in the EAPO to characterise an invention relating to a new medical use. Thus, a claim format such as "a method for the treatment of Y, comprising administering Y in the therapeutically effective amount" is acceptable under the Eurasian patent law to characterise an invention relating to use of a product for a new purpose.

Comment

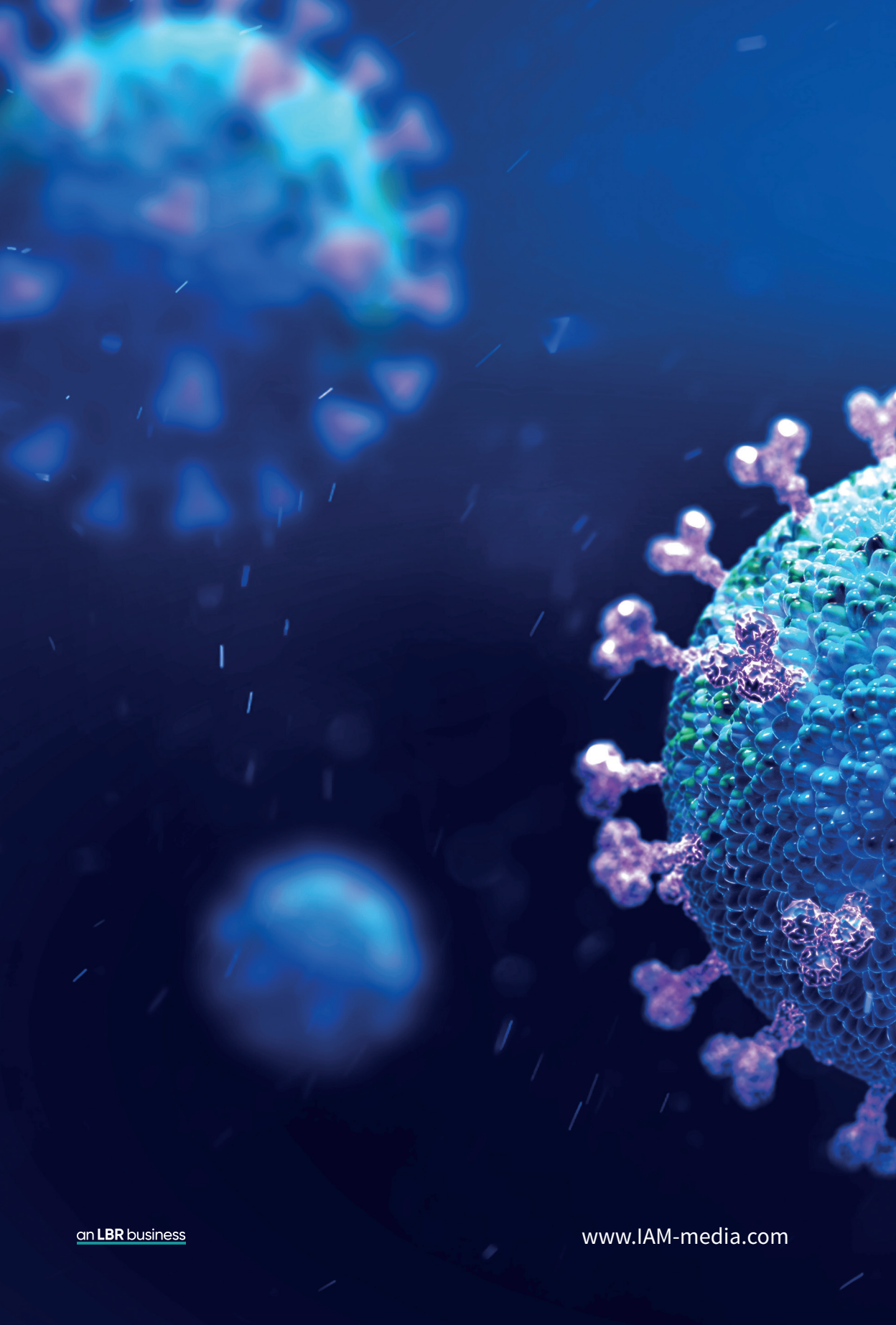
After Russia's Patent Law was changed in 2016, the requirements for the claims were harmonised with the corresponding requirements of the Eurasian Patent Law in respect of the protection of a new medical use of a well-known product. Russia's Patent Law no longer provides an opportunity to protect a known product that differs exclusively in a new purpose, in the format of 'product X for the treatment of Y'. For such inventions in Russia, and in accordance with the Eurasian Patent Convention, only the following claim formats are possible:

- use of X for the treatment of Y;
- use of X for the manufacture of a medicament for the treatment of Y; and
- a method of the treatment of Y, comprising the administration of X.

Such formats relating to use allow the protection of a product for new medical use and are equivalent in terms of the scope of exclusive rights. The indication of features of a regimen of administration or dosage of a product in the

claims formulated as use leads to the classification of such claims as a method of treatment, which is much less preferable in terms of the difficulties that may arise in proving the fact of exploiting the invention. *iam*

Gorodissky & Partners
B Spasskaya str 25, Bldg 3
Moscow 129090
Russia
Tel +7 495 937 6116
Web www.gorodissky.com



an LBR business

www.IAM-media.com