

Inputs of the Russian Federation in response to the SCP Circular 9199

Part I

- Inputs for the preparation of the following documents and a new webpage

(i) Draft reference document on the exception regarding extemporaneous preparation of medicines

Under the laws of the Russian Federation, pharmacy organizations¹ are allowed to manufacture medications².

Since September 1, 2023, the manufacturing pharmacies are allowed to use not only pharmaceutical substances (as it was before) but also medicines included in the State Registers of Pharmaceutical Products for Medical Purposes when preparing medical products. This legal development allows to improve medication management for the patient, reduces the risk of errors in the use of the drug by patients on an outpatient basis, and also reduces the cost for the patient if the prescribed number of doses is significantly less than the minimum number of doses in the registered package.

Furthermore, prescription of a medicine under an individual prescription of a doctor, that is repackaged by a pharmacy organization, changes the legal status of a medicine. In case the instructions for use of a medicine does not contain any relevant indication, however the medical practice indicates that the specified active substance is suitable for the treatment of another disease, the purchase of this medicine may be borne by the State for some groups of citizens. This is especially important for the drug researchers, who can thus study the effect of a medicine on a limited number of patients, which can subsequently become the basis for conducting a clinical trial to expand the medicine instructions. This process is often called "repositioning" of the drug if the indication is fundamentally different from that for which the primary clinical trials were conducted.

Under para. 5 of Art.1359 of the Civil Code of the Russian Federation, the one-time manufacturing of medicines in a pharmacy on a doctor's prescription does not

¹ Under the Order No. 780n of the Ministry of Health of the Russian Federation of July 31, 2020, the pharmacy organizations comprise four types of pharmacies:

1. A retail pharmacy (it may have the right to sell medicines in the finished dosage forms and to manufacture medicinal products (manufacturing pharmacies), including aseptic products);
2. A pharmacy being a structural subdivision of a medical organization (it may have the right to sell medicines in the finished dosage forms, to manufacture medicinal products, and additionally to manufacture aseptic products, and/or radiopharmaceutical medicinal products);
3. A pharmacy point, including as a structural subdivision of a medical organization; and
4. A pharmacy kiosk.

² The Federal Law No. 502-FZ "On Amendments to Art. 56 of the Federal Law "On the Circulation of Medicines" of December 5, 2022, entered into force on September 1, 2023.

constitute an infringement of an invention, utility model or industrial design. In other words, a one-off pharmacy manufacturing according to an individual prescription cannot be regarded as a patent infringement, since it covers such inventions that relate to methods of obtaining medicines and these technical solutions utilize either industrial technological methods of obtaining compounds or compositions comprising medicines which are not used in pharmacies, or relate to methods of medicines, the area of law enforcement which is focused on patients.

(ii) Study on various aspects of the unity of invention, including divisional application

Under para. 1 of Art. 1375 of the Civil Code, a patent invention application should relate to one invention or a group of inventions so linked as to form a single general inventive concept (unity of invention requirement).

In 2023, the legislation of Russian Federation related to the unity of invention requirement, together with the practical approaches used to verify compliance of the claimed invention with this requirement, was amended to bring the requirement and the verification approaches, used by Rospatent, closer to those applied to international applications, filed under the Patent Cooperation Treaty (PCT), and those used by the European Patent Office (EPO) and the Eurasian Patent Office (EAPO).

The relevant amendments are specified in the Regulations approved by the Order No. 107 "On the State Registration of Inventions" of the Ministry of Economic Development of the Russian Federation of February 21, 2023 (with amendments introduced by the Order No. 148 of the Ministry of Economic Development of the Russian Federation dated March 15, 2024, and entered into force on April 25, 2024). The Regulations comprise the following parts:

- Requirements for the Documents of the Application for Granting an Invention Patent (Requirements);
- Regulations for Drafting, Filing and Examination of Documents Forming the Basis for Performing Legally Significant Actions for the State Registration of Inventions.

The rules for combining inventions are set forth in para. 2 and 63-65 of the Requirements. The unity of invention requirement regarding a claimed group of inventions is met when there is a technical linkage between the inventions included in the group of inventions expressed by one or more identical or correspondingly special technical features of an invention (para. 2 of the Requirements).

The technical features of an invention and physical, chemical, biological characteristics, showing the way the invention is similar to or different from another technical solution(s), are listed in para. 44-50(1) of the Requirements.

The special technical features include same or similar characteristics distinguishing each invention from its closest analogue (features that, together with other distinctive characteristics, determine the contribution made to the state of the art by each of the inventions combined in a group).

The identical special technical features include those that coincide in terms of the content. Furthermore, the special technical features comprise mutually dependent features (mutually complementary features that together form a functional unity, for instance flat pins of an electrical plug in one invention of the group and slotted holes of an electrical socket in another invention of the same group).

In addition, there are rules for grouping inventions that must be followed together with the technical relationship between inventions in the group of inventions.

Para. 63 of the Requirements reads as follows:

Taking into account the unity of invention requirement, set forth in para. 2 of the Requirements, the independent claims related to the subject of different types of inventions may be included in the claims in one of the following allowed combinations:

- an independent claim element covering a product, an independent claim element covering a process for making (obtaining) that product, and an independent claim element covering the application/usage of the product;
- an independent claim element covering a product and independent claims covering application/usage of that product;
- an independent claim element covering a process and an independent claim element covering a product designed to perform the process or one of its operations;
- an independent claim element covering a method and an independent claim element covering a product designed to be used in the method;
- an independent claim element covering a product, an independent claim element covering a method to make (obtain) the product, and an independent claim element covering a product designed to use the method.

Para. 64 of the Requirements reads as follows:

Subject to the unity of invention requirement, set forth in para. 2 of the Requirements, the claims may include two or more independent claim elements relating to subjects of inventions of the same type, in one of the following combinations:

- independent claim elements characterizing variants of an invention relating to subjects of the same kind (several devices or substances), for the same purpose, ensuring accomplishment of the same technical result;
- an independent claim element characterizing the subject of an invention as a whole and an independent claim element covering its part;
- an independent claim element characterizing the subject of the invention in general and an independent claim element covering a special case of performance or use of the invention;
- independent claim elements characterizing intermediate and final products;
- independent claim elements covering subjects of an invention that complement each other and interact with each other in the course of an operation.

Para. 65 of the Requirements reads as follows:

The compliance with the unity of invention requirement is checked during the formal examination (without identifying the substance of the invention to the extent that no specialized knowledge is required) and during the substantive examination (Art. 1384(4) and 1386(6) of the Civil Code).

In the course of substantive examination, the verification of compliance with the unity of invention requirement should be carried out in the two following stages (para. 45 of the Regulations):

- before conducting an information search on an application taking into account the closest analogue indicated by the applicant;
- after completion of the information search, taking into account the results of the information search and the closest analogue identified.

If the verification of compliance with the unity of invention requirement shows that the claimed inventions do not contain at least one identical or corresponding special technical feature of the invention that distinguishes each of the inventions from its closest analogue, the inventions of the claimed group of inventions may not be considered to have a technical relationship (para. 45 of the Regulations).

Under para. 46 of the Regulations, when checking whether the inventions, specified in the independent claim elements, are correctly classified as variants, it is necessary to ensure that purposes of the inventions and the technical results, indicated by the applicant, coincide. The requirement of coincidence of the technical results is met if, in addition to the technical result common to all inventions, claimed as variants, a different technical result is indicated for one or more inventions. The requirement of coincidence of technical results is not considered to be violated even if the technical result, common to all inventions, is additionally characterized by a specific feature in respect of any of the inventions of the group.

The IP Office should notify the applicant of non-compliance with the unity of invention requirement and provide the reasons behind such a decision (para. 18 and 45 of the Regulations). The applicant is then invited to indicate which of the claimed inventions (which group of inventions meeting the unity of invention requirement) should be examined and, if necessary, to amend the application documents accordingly.

If the applicant fails to indicate which of the claimed inventions should be examined and to submit a request to amend the application documents accordingly, the substantive examination is carried out in respect of the invention that was the first to be disclosed in the claims or in respect of a group of inventions related to that invention by a single inventive concept (para. 19 and 45 of the Regulations).

In case the applicant files a request for reconsideration of the examination findings that the unity of invention requirement was not met, providing arguments and explanations that, in the applicant's opinion, confirm fulfillment of this requirement, the application should be substantially examined taking into account the results of the consideration of the said request (para. 45 of the Regulations).

If the unity of invention requirement is not met, the applicant may file a divisional application (or applications) under Art. 1384(4) of the Civil Code. The priority date of the invention covered by the divisional application should be the date of filing of the original application disclosing the invention by the same applicant, or, if there is a right to an earlier priority date for the original application, this should be the date of that priority, at the same time maintaining the priority of the invention (Art. 1381(4) of the Civil Code).

In a notification of non-compliance with the unity of invention requirement, Rospatent informs the applicant of the possibility to file divisional application(s) (para. 18-19 and 45 of the Regulations).

(iii) Compilation of laws and practices relating to the patentability of artificial intelligence (AI)-related inventions (update of document SCP/30/5)

Currently, there are no provisions in the Russian legislation that establish a special procedure for examining the AI-related applications. General provisions governing the procedure for examination of invention applications are then applied.

Under para. 50 of the Regulations for Drafting, Filing and Examination of the Documents Forming the Basis for Performing Legally Significant Actions for the State Registration of Inventions (Annex No. 1 to the Order No. 148 of the Ministry of Economic Development of the Russian Federation of March 14, 2023), in course

of the examination, Rospatent determines whether the claimed solution is covered by the list of solutions unprotectable as inventions under para. 5 of Art. 1350 of the Civil Code.

(iv) Dedicated webpage on the expedited examination program of Intellectual Property Offices (updating the contents of document SCP/35/6)

In order to update the information about the Russian Federation, the following amendments should be done in Table 1 (Types of Expedited Examination Programs provided by IPOs) and in paragraphs 125-129 of the document SCP/35/6:

- delete the reference to the Russian Federation from the COVID-19 section, since Rospatent is not currently providing an accelerated examination of invention and utility model applications covering solutions against COVID-19;
- supplement the mentioning of the Russian Federation in the Applications Filed by Small and Medium-Sized Enterprises/Startups/Venture Businesses or Others section with the priority examination of applications for inventions and utility models filed by small technology companies;
- add that Rospatent continues to participate in the Patent Prosecution Highway (PPH) program and the Global PPH, and that Rospatent and CNIPA extended their bilateral PPH program from July 1, 2023 for an indefinite period of time.

(v) Document updating SCP/26/5 (constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impact on the access to affordable especially essential medicines for public health purposes in those countries)

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(vi) Document updating SCP/25/4 (compilation of court cases with respect to client-patent advisor privilege)

The Federal Law No. 416-FZ dated December 21, 2021, introducing the privilege of the patent attorneys, protects any information about the activities of the client and the rights to the results of intellectual activity that became known to the patent attorney (or his employer) during his work.

The secrecy obligation also extends to other employees of that employer, which is aimed at increasing the confidence of the client in the attorney. At the same time, a patent attorney is obliged to provide information requested by a public authority of the Russian Federation.

(vii) Document updating SCP/32/6 (patent law provisions that contribute to effective transfer of technology including sufficiency of disclosure)

Under Art. 1375 of the Civil Code of the Russian Federation, an application for an invention patent should contain a description of the invention disclosing its essence sufficient to enable a person skilled in the art to carry out the claimed invention.

In accordance with Art.1386 (2) of the Civil Code, the substantive examination of an invention application should include verification of the sufficiency of disclosure of the essence of the claimed invention provided in the application documents, specified in subpara. 1-4 of Art. 1375(2) of the Civil Code (patent application, invention description, claims, drawings and other materials if they are necessary to understand the essence of the invention).

Currently, the requirements for the information to be provided in the application in order to ensure compliance with the sufficiency of disclosure requirement are set forth in the Requirements for the Application Documents for an Invention Patent (Requirements), approved by Order No. 107 "On the State Registration of Inventions" of the Ministry of Economic Development of the Russian Federation dated February 21, 2023 (as amended by Order No. 148 of the Ministry of Economic Development of the Russian Federation dated March 15, 2024, and entered into force on May 25, 2024).

Taking into account the law enforcement practice existing in the Russian Federation, the approaches to verifying compliance with the sufficiency of disclosure requirement were clarified in Regulations for Drafting, Filing and Examination of Documents Forming the Basis for Performing Legally Significant Actions for the State Registration of Inventions approved by Order of the Ministry of Economic Development of Russia No. 107 "On the State Registration of Inventions" dated February 21, 2023.

Compliance with the sufficiency of disclosure requirement is checked in accordance with para. 53-57 of the Regulations. Under para. 53 of the Regulations the following aspects should be verified:

- 1) whether the purpose of the invention is indicated;
- 2) whether the technical problem to be solved by the invention and the technical result to be obtained are indicated;
- 3) whether the set of essential features necessary to achieve the technical result indicated by the applicant is disclosed;
- 4) whether at least one example of implementation of the invention is provided. The example should confirm by experimental data or theoretical justification of the possibility to achieve the purpose of the invention, including the of the technical result;

- 5) whether the application documents referred to in subpara. 1 to 4 of para. 2 of Art. 1375 of the Civil Code or in the state of the art as of the date of filing of the application disclose methods and means by means of which it is possible to carry out the invention with realization of the purpose as characterized in each of the claims including in the case of the use of general concept(s) to characterize the feature(s);
- 6) whether an example of the invention is given showing how the invention can be carried out using at least one particular form of realization of the feature expressed by the general concept, or at least one value of a parameter within an interval, if at least one general concept or an interval of values of a parameter is used in the claims to characterize a feature of the invention. The example should confirm by experimental data or theoretical justification of the possibility of realizing the purpose of the invention with the achievement of a technical result using at least one precise form of realization of the feature, expressed by the general concept or one parameter value, included in the interval of parameter values.

In case the application documents, referred to in subpara. 1 to 4 of para. 2 of Art. 1375 of the Civil Code, do not contain information on the methods and means necessary to carry out the invention, the said information may be described in a source that became publicly available before the filing date of the application or, if the application claims a priority earlier than the filing date, before the priority date of the invention (para. 54 of the Regulations).

Compliance with the sufficiency of disclosure is checked by taking into account the provisions of the Requirements for the Disclosure of the Essence of the Invention and for the Disclosure of the Possibility to Carry out the Invention (para. 54 of the Regulations). At the same time, where the claims contain several features expressed by common terms, the test in accordance with subpara. 5 and 6 of para. 53 of the Regulations, should be carried out with respect to each of these features. If the invention achieves two or more technical results, the test under subpara. 3, 4 and 6 of para. 53 of the Regulations is carried out with respect to each technical result.

Pursuant to para. 55 of the Regulations, if, as a result of the examination, it is established that the application documents provided for in subparagraphs 1 to 4 of para. 2 of Art. 1375 of the Civil Code and submitted on the date of filing of the application do not meet the requirements set forth in subpara. 1, 3 and 5 of para. 53 of the Regulations, namely, there is no information on the purpose of the invention, or all essential features necessary to achieve the technical result are not disclosed, or methods and means necessary to realize the invention are not disclosed either in the application documents or in the state of the art as of the filing date of the application (as of the requested priority date), and the applicant's arguments do not change the

conclusion that the disclosure of the essence of the invention is not sufficient, a decision should be made to refuse the issuance of such a patent.

Pursuant to para. 56 of the Regulations, if as a result of the examination it is established that the application documents, provided for in subparagraphs 1 to 4 of para. 2 of Art. 1375 of the Civil Code and submitted on the date of filing thereof, do not contain at least one example, specified in subpara. 4 and 6 of para. 53 of the Regulations showing how the invention may be carried out, including the use of at least one specific form of carrying out a feature expressed in the claims by a general concept, or the use of the value of a parameter from the range of parameter values given in the claim, and the applicant's arguments do not change the conclusion about the inconsistency of the sufficiency of disclosure of the essence of the invention, a decision should be made to refuse the issuance of such a patent.

In case an example is provided but it does not comply with the requirements of para. 53(4) and (6) of the Regulations (in particular, it does not contain experimental data or theoretical justification of the possibility of accomplishing the purpose of the invention with the achievement of a technical result, including the use of at least one particular form of implementing a feature, expressed by a general concept, or one value of a parameter falling within the range of values of the parameters, specified in the claims, or the example does not confirm the possibility of carrying out the purpose of the invention with the achievement of a technical result, or it does not possibility to achieve the purpose of the invention with the achievement of a technical result, then the applicant should be proposed to submit additional documents.

If the applicant's use of a general concept or an interval of values of a parameter is not justified (for example, because the examples of embodiments given in the description of the invention are insufficient to confirm the possibility of achieving the purpose of the invention with obtaining the technical result, indicated by the applicant over the entire range of values claimed), the applicant is invited to submit additional materials.

At the same time, in case the applicant was invited to submit additional materials, he/she should be informed that the newly submitted examples would be considered as additional ones, however, these examples may not supplement the description of the invention. Furthermore, it should be indicated that, if a patent is granted, any interested person will be able to familiarize himself/herself with the application document, including the additionally submitted materials.

Pursuant to para. 57 of the Regulations, if, based on the examination results, it was established that the application documents, provided for in subpara. 1-4 of para. 2 of Art. 1375 of the Civil Code and submitted on the date of filing of the application, do not indicate the technical problem to be solved with the invention, do not indicate

the technical result accomplished by the invention or it does not result from the description of the invention for a specialist, than the examination of the application should be carried out taking into account the fact that the technical problem may consist of the expansion of the means for a certain purpose that is solved by creating a technical result of the invention.

In this case, the combination of features of the invention necessary for the invention to fulfil the purpose indicated in the generic concept is determined, while the features of the invention contained in the claims which are not necessary for the invention to fulfil its purpose are considered to be immaterial.

Thus, the results of the test of compliance with the requirement of sufficiency of disclosure of the nature of the invention may reveal avoidable and irrecoverable infringements. The presence of irrecoverable infringements of the requirement of sufficiency of disclosure of the nature of the invention is an independent ground for Rospatent to refuse to grant a patent of the Russian Federation for the invention.

(viii) Study on patent inventorship and ownership issues arising from collaborative research.

The Civil Code provides for the rules on patenting the inventions or utility models, created by joint efforts, and disposing the exclusive right to such results of intellectual activity. Art. 1348 of the Code specifies the following:

- citizens, who have jointly created an invention or utility model, should be recognized as co-authors;
- each of the co-authors should have the right to use the invention or utility model at his/her own discretion unless otherwise provided by agreement between them;
- the right to obtain patent for invention or utility model should be jointly exercised by the co-authors;
- each of the co-authors has the right to take independent measures to protect his rights to the invention or utility model.

Para. 3 of Art. 1229 of the Civil Code applies to the relations among co-authors related to the distribution of income obtained from the use of invention, utility model or industrial design and the disposal of the exclusive right to invention or utility model. Under this provision, the income from the joint use of a result of intellectual activity or from the joint disposal of the exclusive right to such a result should be distributed among all right holders in equal shares, unless otherwise provided by agreement between them.

Under para. 5 of Art. 1358 of the Civil Code, if the two or more persons hold the right to a patent for an invention or utility model, regardless of whether any of the patentees is the author of this intellectual activity result, para. 2 and 3 of Art. 1348 of the Civil Code should apply to the relations among them as follows:

- each of them should have the right to use the invention or utility model at his/her own discretion, unless otherwise provided by agreement between them;
- disposal of the exclusive right to the invention or utility model should be made jointly, unless otherwise provided by agreement between them.

Part II

- Inputs of the Russian Federation for the updated information on the following topics:

(i) Certain aspects of the applicable national or regional patent law, related to prior art, novelty, inventive step (non-obviousness), grace period, sufficiency of disclosure, exclusions from patentable subject matter and/or exceptions and limitations of the rights

There have been no updates on this matter since the last year submission.

(ii) National and regional laws on opposition systems and other administrative revocation and invalidation mechanisms

There have been no updates on this matter since the last year submission.

(iii) International worksharing and collaborative activities for search and examination of patent applications

Rospatent continues the relevant bilateral expert cooperation with several foreign IP Offices upon request.

Furthermore, Rospatent is exchanging the results of information search and examination of the applications covering the same solutions with the Eurasian Patent Office.

(iv) Compilation of laws and practices regarding the scope of client attorney privilege and its applicability to patent advisors

There have been no updates on this matter since the last year submission.