(i) Additional inputs of the Russian Federation for the preparation of a draft reference document on the exception regarding the use of articles on foreign vessels, aircrafts and land vehicles

Exceptions related to the use of patent law objects on foreign vessels, aircraft and land vehicles are specified in Article 1359 of the Civil Code of the Russian Federation.

Under Article 1359 of the Code, the following actions do not infringe the exclusive rights to inventions, utility models or industrial designs:

"the use of a product or article that comprises an invention, utility model or industrial design as part of the design, auxiliary equipment or used in the operation of vehicles (water, air, road or rail means of transport) or spacecraft of the foreign States, provided that such a vehicle or spacecraft is temporarily or accidentally on the territory of the Russian Federation and that the product or article is used only for the needs of the vehicle or spacecraft. The mentioned actions are not recognized as a violation of the exclusive rights in respect of vehicles or spacecrafts of those foreign States that grant the same rights in respect of vehicles or spacecrafts registered in the Russian Federation".

No information is available to Respatent regarding any difficulties in the application of the mentioned provisions of the Civil Code, nor any court decisions related to these matters.

(ii) a further study on the sufficiency of disclosure (Part II), relating to inventions having an experimental nature in unpredictable art, such as chemistry and biotechnology, and any other areas that deserve special attention, as proposed in document SCP/31/8 Rev

Under Article 1375 of the Civil Code of the Russian Federation, a patent application for an invention shall contain a description disclosing the claimed solution in a

sufficiently clear and complete manner to allow a person skilled in the art to repeat this invention.

Requirements for applications for inventions, in particular, for their descriptions, are set forth by the Requirements for Materials of Patent Applications for Inventions, approved by the Order of the Ministry of Economic Development of Russia No. 316 of May 25, 2016 (Requirements).

According to Article 1386 of the Civil Code, the sufficiency of disclosure, presented in the patent application, shall be checked during the substantive examination.

The description section of the patent application comprises two subsections titled "Invention Essence Disclosure" and "Invention Implementation", where the applicant shall provide necessary data on the disclosure of the invention and the way a person skilled in the art may make it (specified in Order No. 316 of the Ministry of Economic Development of Russian Federation).

The second subsection of the description shall contain data on how an invention could have been made by a person skilled, bearing in mind the invention's purpose and confirming its capability to achieve the technical result, by providing a detailed description of at least one example of the invention with reference to graphic materials, if any. This data shall include objective materials obtained from experiments, tests or assessments accepted in related technology, or theoretical justifications based on scientific knowledge.

The Requirements specify precise information that shall be provided in the application materials for various types of objects related to chemistry, pharmaceuticals and biotechnology, such as substance, composition, method, application, strain, etc.

The following data shall be disclosed in the patent application covering <u>substance</u> (various compounds or compositions) and methods of obtaining chemical <u>compounds</u>:

- 1). for an invention relating to a chemical compound with an established structure, a structural formula, proven by known methods, physical and chemical constants, the method to obtain the compound and the invention feasibility for the indicated purpose shall be described;
- 2). in case the chemical compound was obtained using a microorganism strain, plant or animal cell line, a method of its production involving that strain, cell line, their data and, if necessary, data on deposit shall be described;
- 3) for a biologically active compound, a quantitative characteristic of activity, and, if necessary, data on the selectivity of action and other indicators shall be described;
- 4). if an invention relates to drugs for the prevention and/or treatment of certain human or animal diseases, reliable information shall be provided, indicating the effect of the drug on the disease etiopathogenesis or the state of the human/animal body. For an invention relating to drugs for the diagnosis of a particular human or animal condition or disease, data shall refer to the relevant diagnostic factor. Other reliable information may also be provided to prove that the claimed drug is suitable for the treatment or prevention of the specified disease or condition (obtained, in particular, by experiments based on adequate models);
- 5). for an invention related to a medicinal product, information on the dosage form shall be provided;
- 6). in case an invention relates to a chemical compound that is a form of a known chemical compound (in particular, an isomer, stereoisomer, enantiomer, amorphous or crystalline form) or its derivatives (in particular, a salt, solvate, hydrate, complex compound or ester), the information on its new features compared to the known compound in qualitative or quantitative

terms, that are not clearly apparent to the person skilled in the art, and the evidence of these new features, shall be provided.

If a certain form or derivative of a known chemical compound shows biological activity suitable for the prevention and/or treatment of certain human or animal diseases, then data showing its impact on the disease etiopathogenesis or the body condition shall be provided.

In case a certain form or derivative of a known chemical compound demonstrates biological activity suitable for diagnosing a certain human or animal condition or disease, the information shall refer to the relevant diagnostic factor.

Other data, confirming that a particular form or derivative of a known chemical compound is suitable for the prevention, diagnosis and/or treatment of a specified human or animal disease or condition (obtained, in particular, in experiments based on adequate models), may also be provided;

7). if an invention relates to several or a group of chemical compounds with an established structure, described by a general structural formula, then the ability to obtain all compounds shall be confirmed by providing a general scheme of the obtaining method and an example of obtaining a specific compound, and if the group includes compounds with radicals of different chemical nature, then examples sufficient to confirm the ability to obtain the compounds with these different radicals.

For the compounds obtained, their structural formulas, confirmed by known methods, physicochemical constants and evidence, that the invention is capable to serve the indicated purpose with the confirmation of such a capability in relation to some compounds with radicals of different chemical nature, shall also be provided.

If compounds are biologically active, then indicators of their activity and, if necessary, selectivity of actions and other indicators are given;

- 8). in case the invention relates to an intermediate compound, the capability to process it into a known end product or to obtain a new end product from it with a specific purpose or biological activity, shall be provided;
- 9). if the invention relates to a nucleic acid, protein, polypeptide or peptide isolated from a natural source or obtained in another way with the same or a specifically altered biological function, then a sequence number in the sequence listing, a biological function (type of activity, biological feature) determining the purpose, physicochemical and other characteristics that allow distinguishing the claimed nucleic acid, protein, polypeptide or peptide from others, the method of obtaining the substance and its suitability for a particular purpose shall be described;
- 10). a nucleotide or amino acid sequence shall be presented by indicating its number in the sequence listing as "SEQ ID NO ..." followed by the relevant free text if the sequence characteristic in the sequence listing is given using such text;
- 11). in case the invention relates to a composition (e.g., mixture, solution, alloy, glass), then examples specifying the ingredients included in the composition, their characteristics and quantitative contents shall be provided. The method of obtaining the composition and, if it contains a new substance as an ingredient, the method of obtaining this ingredient shall be also described.

If an ingredient of the composition is expressed as a group of chemical compounds described by a common structural formula, then examples of compositions containing chemical compounds with radicals of different chemical natures shall be given with the confirmation of its suitability for the indicated purpose.

In the examples given, the content of each ingredient shall be indicated in such a single value that is within the range of values indicated in the formula of the invention (when expressing the quantitative content of the ingredients in the formula as a percentage (by weight or by volume), the total content of all the ingredients indicated in the examples shall be equal to 100%).

The following data shall be disclosed in the patent application, covering the <u>method</u>, to confirm the possibility of carrying out the invention:

- for an invention related to a method of obtaining a group (series) of chemical compounds described by a common structural formula, an example of how the compounds of the group (series) can be obtained using this method shall be given, and if the group (series) includes compounds with radicals of different chemical nature, then such many examples shall be given that is sufficient to confirm the capability to obtain compounds with these different radicals. Structural formulas confirmed by known methods and physicochemical characteristics shall be provided for the obtained compounds included in the group (series), and data on the purpose or biological activity shall also be provided for unknown compounds and for known compounds for which purpose has not been established yet;
- or inventions related to methods of obtaining chemical compounds with undefined structure or mixtures of undefined composition and characteristics, allowing to distinguish these compounds from others, data on initial reagents for obtaining compounds or mixtures, confirming the suitability of these compounds or mixtures for the purpose, in particular, on the characteristics, determining such a purpose, shall be provided.

To confirm the possibility of carrying out an invention related to the <u>use of a substance for a specific purpose</u>, the information, confirming the possibility of the applied substance to fulfill this purpose, shall be provided, and if the applied object is unknown, the data, sufficient to obtain it, shall also be disclosed.

The following information shall be provided in the patent application for biotechnology-related inventions:

1). For the invention related to a strain (microorganism strain, plant or animal cell line, strain consortium), the method of obtaining the strain shall be provided in the description.

If the strain is natural, then the certificate of deposit of the strain, specifying the name or abbreviation of the depositary collection and its address, the generic and species name of the biological object in Latin (according to the international nomenclature), the registration number assigned by the collection to the deposited object, date of the deposit that shall not be done later than the application date or priority date if claimed. For genetically engineered strains, the provision of the certificate of deposit is not mandatory.

A confirmation of the possibility of the strain to fulfill its purpose with the achievement of the technical goal, the technical result achievement shall be provided, including an example of carrying out the invention (e.g., a high product output, produced by the strain, may be demonstrated).

2). For an invention related to a method in the field of biotechnology (for example, a method to obtain a transgenic plant), the description of the invention shall contain the sequence of actions over a material object using material means, including examples of implementation of the invention.

All means shall either be known from the prior art or be sufficiently described (the method of their obtaining is disclosed, and if natural strains are used in the method, then data on the deposition of strains shall be provided).

At the same time, the possibility of the method to fulfill its purpose and to achieve the technical result (for example, demonstrating the possibility to obtain a plant with some improved feature) shall be proven.

3). For the invention related to a substance in the field of biotechnology (for example, nucleic acid, protein, including an antibody), the description of the

invention shall indicate a method to obtain the substance, its structural characteristics (or physicochemical and other features allowing to distinguish the claimed substance from the prior art), the capability to serve its purpose confirming the technical result (for example, the possibility of binding to the antigen epitope with a high degree of efficiency shall be demonstrated), including the examples of carrying out the invention.

- 4). For a genetic construction (e.g., expression vector, host cell, transgenic plant), the invention description shall comprise examples of its carrying out, a method to obtain the construction, data related to the constructive performance, demonstration that the invention can fulfill its purpose (data confirming the capability to serve the purpose or to perform the biological function that determines the purpose) achieving a technical result (for example, for the host cell, a high output of the produced substance shall be shown).
- 5). For a composition (for example, a seed treatment composition containing a microorganism), the invention description shall contain data that discloses the composition and the quantitative content of the components, including the examples. The method to obtain the composition shall also be described. If the composition contains a new substance, then the method to obtain this substance shall be described. The capability of the composition to serve its purpose by achieving a technical result (e.g., seed treatment efficacy) shall be demonstrated.
- 6). For the invention covering a use/application, the description shall provide data confirming that the invention is capable to serve its purpose, including the examples, and if the use/application object is unknown, then the data on its obtaining shall be provided.

(iii) a document compiling information relating to the expedited examination programs of IP offices, including information on Prioritized Examination of COVID-19 related patent applications

Rospatent is constantly working on reducing the examination pendency, in particular, for inventions and utility models.

The applicants can now interact with the IP Office online, for instance, they may file applications or obtain assistance regarding the filed applications 24/7. The documents contained in the users' personal accounts, including the examination results, are updated immediately. Furthermore, the e-filing minimizes the risk of speeding the viral infection and saves the applicants' financial resources, since the e-filing fee is 30% less than in the ordinary one and all communication regarding the applications does not require the purchase of paper or sending letters by post.

The pandemic, that swept the world in 2020, set a new vision for the development of many areas of science. The need to quickly adapt to the new realities of life has increased the importance to speed up the process of obtaining advanced data related to the latest developments.

In April 2020, Rospatent launched a pilot program for prioritized examination of applications related to technologies aimed at combating viruses and related diseases (pneumonia), or the Fast-Track Examination Procedure, to support the development of scientific and technological solutions playing a key role in the fight against COVID-19.

In May 2020, the Rospatent subordinate entity, the Federal Institute of Industrial Property (FIPS) created an information section titled "COVID-19" on its official website to provide users with information on patent documents of the Russian Federation, filed by both resident and non-resident applicants from 2000 until now. The website section is constantly updated and comprises the following subsections:

- Antiviral drugs
- Viral disease diagnostics

- Medical products
- Protective equipment
- Sterilizing and disinfecting agents

In 2021, Rospatent extended the list of prioritized areas for the Fast-Track Examination Procedure to include the following:

- Antiviral therapy
- Vaccines against viral infections
- Diagnostic test systems for infectious diseases and their components
- Respiratory medical products (e.g. ventilators, inhalers, intubation tubes)
- Personal protective equipment (e.g. medical masks, respirators, protective suits)
- Sterilizing and disinfecting technologies
- Genome editing technologies
- Smart information systems for medicine and healthcare
- Telemedicine
- Supercomputer technologies

The initiative of the Russian IP Office is implemented within the existing public services without charging any additional fees.

The Fast-Track Examination Procedure allows the resident inventors, working in the prioritized areas of science and technology, to obtain patent protection if they are ready to commercialize their inventions.

From April 2020 (the beginning of the COVID-19 pandemic) February 28, 2023, Rospatent received 1 178 applications related to the technologies for combating viruses and related diseases, including 880 inventions and 298 utility models. The

average timeline for the first Office action during the substantive examination amounted to 28 days.

Furthermore, Rospatent may carry out an information search on these applications in 10 working days. The use of the search results during the examination allows to reduce the period needed to communicate the first examination-related correspondence to the applicants up to 2 months for the inventions and utility models applications, and to reduce accordingly the total pendency before the final decision regarding the applications.

Information search for the Fast-Track Examination Procedure is carried out based on concluded contracts. Any applicant may use this service by paying an additional fee. The cost depends on the number of International Patent Classification groups.

(iv) a compilation on how jurisdictions around the world address the issue of artificial intelligence (AI) inventorship through jurisprudence, legislation and practice. In this context, Member States and Regional Patent Offices are kindly invited to transmit inputs with regard to the general concept of inventorship, including employee inventors and joint inventors, as well as the application of that concept to inventions by AI.

The general concept related to the authorship of the inventions in the Russian Federation

The Russian doctrine of IP law in general and patent law in particular provides that the result of intellectual activity appears due to the creative contribution of a human being. Under Article 1228 of the Civil Code, an author of the result of an intellectual activity is a citizen whose creative work resulted in such a result. Following Article 1347 of the Code, the author of an invention, utility model or industrial design is the citizen whose creative work created the corresponding result of intellectual activity.

Under Article 1348 of the Code, the citizens who jointly created an invention, utility model or industrial design are recognized as co-authors who jointly dispose of a right

to obtain a patent for the invention, utility model or industrial design. Each of the co-authors is entitled to protect his/her rights to the invention, utility model or industrial design.

As a general rule, the right to obtain a patent for an invention, utility model or industrial design is initially owned by its author. The right to obtain a patent for an invention, utility model or industrial design may be transferred to another person (successor) or may be assigned to another person in the cases and on the grounds stipulated by law, including universal succession or under a contract, including an employment contract (Article 1357 of the Code).

While filing a patent application for an invention, utility model or industrial design, the surname, first name and, if exist, patronymic of the author or authors shall be indicated. However, the requirement to indicate the author of the invention is formal and Rospatent does not check the correctness or completeness of such an indication. Under Article 1347 of the Code, the person, indicated as the author in a patent application for an invention, utility model or industrial design, is considered as its author, unless otherwise proven. Following Article 1406 of the Code, any dispute about the authorship of an invention, utility model or industrial design, shall be considered by the court.

Employee inventions (or service inventions)

Under Article 1370 of the Code, an invention, utility model or industrial design, created by an employee in the course of his/her employment duties or a specific task of the employer, shall be recognized as an employee invention, utility model or industrial design. According to Article 1370 of the Code, the exclusive right to an employee invention, utility model or industrial design and the right to obtain a patent belongs to the employer, unless the employment or civil law contract between the employee and the employer provides otherwise.

An invention, utility model or industrial design, created by an employee using the employer's financial, technical or other material resources but not in connection with his/her employment duties or a specific task of the employer, shall not be recognized as employee inventions. The right to obtain the patent and the exclusive right to such an invention, utility model or industrial design belongs to the employee. In this case, the employer has the right to demand a free simple (non-exclusive) license to use the created result of intellectual activity for his/her own needs for the entire duration of the exclusive right or reimbursement of expenses incurred by him/her in connection with the creation of the invention, utility model or industrial design.

Concepts of authorship of inventions created by artificial intelligence and potential rights holders of these inventions

In the Russian Federation, there was no consensus on who should be considered the author of an AI-created invention and who should own the exclusive right to use such an invention. Scholars and researchers note the following concepts in this regard:

- author of an invention shall be the AI developer
- author shall be a person who arranged the functioning of the AI and contributed to the research area of the results of intellectual activity, including investor
- author shall be the AI user
- invention shall be subject to related rights of the AI creator and user
- AI and a human being shall be co-authors of the invention
- author of the invention shall be the AI
- fictitious authorship
- invention shall be in the public domain

They also considered a concept of IP rights regime for the AI-created inventions when the AI acts as an employee and the inventions are recognized as the employee ones.

Scholars and researchers note a significant similarity between the employeremployee relationship and the one between the AI system and the person who develops it: an employee, being an independent creative person, who performs work on behalf of his/her employer, is similar to an AI that is independent in its creative nature so much that it has no equal among any computer technologies, creating work with the assistance of its developer/owner, like the employer's contribution that guides the employee and provides the needed resources to do the work.

Nevertheless, bearing in mind the Russian IP laws in force, the above-mentioned concept is rather controversial. To implement this approach, it would be necessary to recognize the right of an AI to be an author of an invention, which is contrary to the existing authorship concept and mentioned provision of the Civil Code, specifying that a citizen (i.e. a human being), whose creative work resulted in the invention, shall be recognized as the author of the invention.

Law enforcement related to the AI-created inventions

At the moment, there is no court practice covering the authorship of AI-created inventions in the Russian Federation.

Rospatent received one application indicating a computer program as the author of the invention. Under Article 1347 of the Civil code, the IP Office asked the applicant to indicate a citizen, who created the invention, as the author based. Since the applicant did not provide the required data, the application was recognized as withdrawn.