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Note C. 9089
Inputs for the preparation of documents to the 34th Session of the Standing Committee on the Law of Patents [1]

BRAZIL

A study on the sufficiency of disclosure, as proposed in document SCP/31/8 Rev.

The analysis on the sufficiency of disclosure is already regulated in the INPI guidelines, particularly in the following excerpts from the documents:

(i) Guidelines for Examination of Patent Applications, Block I, Paragraphs 2.03, 2.13 to 2.19, 2.21, 2.22, 2.38, 2.39, 2.41 to 2.46, 3.10, 3.38, 3.39, 3.53 and 3.85 to 3.97 (INPI Resolution No. 124, of December 04, 2013).

(ii) Guidelines for Examination of Patent Applications, Block II, Paragraphs 5.24 to 5.30, 6.2 to 6.4, 6.9 to 6.14 and 7.1 to 7.23 (INPI Resolution No. 169, of July 15, 2016).

(iii) Guidelines for Examination of Patent Applications - Chemistry, Items 2.4, 3.1, 3.2, 4.1, Item 5, 7.1 and 9.1.3 (INPI Resolution No. 208, of December, 2017).

(iv) Guidelines for Examination of Patent Applications in the Biotechnology Area, Item 2.2 (INPI Normative Instruction No. 118, of November 12, 2020).

(v) Guidelines for Examination of Patent Applications involving Computer Implemented Inventions (CII), Paragraph [037], (INPI/PR No. 411/2020).

The guidelines, in the context of sufficiency of disclosure, represent how the patent examiners will evaluate the patent application, clarifying how the description must be presented so that a skilled person in the art can carry out the claimed invention. It is worth mentioning that these parts of the guidelines are based on the legal framework, with the objective of clearly detailing how

[1] The answers to this Note have been provided on behalf of Brazil by Brazilian National Institute of Industrial Property (INPI).

INPI interprets the condition of sufficiency of disclosure, enabling a harmonized understanding between all the actors involved (State, Society and Judiciary).

It should be noted that INPI is constantly updating the documental framework to improve the analysis of patent applications in technological sectors in which the fulfillment of sufficiency of disclosure deserves special attention, such as: Artificial Intelligence (AI), microorganisms and Chemistry. Next, the main points of the regulations currently in force will be presented, which are used as a subsidy for the analysis of the sufficiency of disclosure at INPI.

DEFINITION

According to Industrial Property Law - IPL (Law No. 9279, of May 14, 1996), the condition of sufficiency of disclosure is provided for in Article 24:

> Article 24 - The description must describe the subject matter clearly and sufficiently so as to enable a person skilled in the art to carry it out and to indicate, when applicable, the best mode of execution.
>
> Sole Paragraph - In the case of biological material essential for the practical execution of the subject matter of the application, which cannot be described in the form of this Article and which has not been accessible to the public, the description will be supplemented by a deposit of the material in an institution authorised by INPI or indicated in an international agreement.

In this way, the Applicant shall disclose the invention in such a way that all the necessary elements and means are present for a person skilled in the art to understand, perform and use the invention. The description must not mislead the person skilled in the art or encourage him/her to carry out undue experimentation.

It is worth noting that sufficiency of disclosure does not oblige the inventor to teach all the details involved in the state of the art in the field of the invention. The function of the description is not to disclose all the scientific phenomena behind the technical results, but to give all the means

and details necessary to allow a person skilled in the art to realize the invention protected by the patent.

In this scenario, the condition of sufficiency of disclosure must be evaluated based on the description, which must present the invention in a sufficiently clear and precise way, to the point of being reproduced by a person skilled in the art. Also, the description must contain sufficient conditions to guarantee the accomplishment of the claimed invention.

It is worth noting that the sufficiency of disclosure aspects are not restricted to Article 24 of the IPL, since the Legislator has pointed out in other articles the importance of the description as a fundamental element for a patent to effectively fulfill its role. In Chapter V, Section I, Article 41 of IPL makes evident the relationship between the scope of the patent, represented by the claims, and the need for interpretation based on the description:

> Article 41 - The extension of the protection conferred by a patent will be determined by the content of the claims, interpreted in the light of the description and drawings.

Another important aspect of sufficiency of description is addressed in Article 50 of the IPL, which makes it clear that a patent that does not comply with the provisions of Article 24 of the IPL will be revoked:

> Chapter VI
>
> Section II
>
> Art. 50 - The nullity of the patent will be declared administratively when:
>
> II – the description and the claims do not meet the provisions of Articles 24 and 25, respectively.

PERSON SKILLED IN THE ART

The definition of the skilled person is broad. The skilled person can be the one with average knowledge of the technique in question at the time of filing the patent application, with technical-scientific level, and/or the one with practical operational knowledge of the subject matter. It is

considered that he/she had the means and the capacity for routine work and experimentation, usual to the technical field in question. There may be cases where it is more appropriate to think in terms of a group of people, as in the case of a production or research team. This can be applied, particularly, in certain technologies with multidisciplinary characteristics, such as: artificial intelligence, computers and nanotechnology. It should be noted that the definition of the person skilled in the art used for the purpose of evaluating the condition of sufficiency of disclosure is the same used for the analysis of the inventive step (patentability requirement).

SUFFICIENCY OF DISCLOSURE EVALUATION

For the purpose of meeting the condition of sufficiency of disclosure, it must be ensured that the patent application contains sufficient technical information to enable a person skilled in the art:

(i) put the invention into practice, as claimed, without undue experimentation; and

(ii) understand the contribution of the invention to the state of the art to which it belongs.

It is understood by “undue experimentation” when a person skilled in the art, based on what is disclosed in the patent application, needs additional experimentation to carry out the invention.

It is important to note that the technical information considered as essential to the reproduction of the claimed invention shall be contained in the application at the time of filing. Although amendments to the description are allowed to be done at any time in order to better describe the state of the art or to eliminate inconsistencies in the text, modifications aimed at introducing essential features of the invention, that were not initially presented, are not authorized. The inclusion of data, parameters or characteristics of the invention that were not included in the originally filed application constitutes an addition of subject matter and, as such, cannot be accepted. (INPI Resolution No. 124, of December 04, 2013, Paragraphs 2.21 e 2.22).

GENERIC STATEMENTS

The use of generic expressions in the description, such as vague and imprecise terms that imply the expansion of the claimed subject matter will not be admitted, based on article 24 of the IPL. In particular, objection will be raised to any expression referring to the expansion of protection to cover the “spirit” of the invention. Objection will also be raised to a “combination of features” or to any expression implying that the invention refers not only to the combination as a whole, but also to individual features or their sub-combinations (INPI Resolution No. 124, of December 04, 2013, Paragraphs 2.38 e 2.39).

It is important to note that the patent claims must represent appropriate generalizations of one or more particular examples contained in the description. The degree of generalization allowed is evaluated on a case-by-case basis in the light of the state of the art. If the information contained in the description is understood to be insufficient, so as not to allow a person skilled in the art to reproduce the claimed subject matter, through the use of routine methods of experimentation or analysis, the examiner may request the presentation of elements that prove that the patent application complies with the condition of the sufficiency of disclosure. In the absence of proof of sufficiency of disclosure for the totality of the claimed subject matter, the reformulation of the claims may be requested, in order to remove the subject matter insufficiently described. (INPI Resolution No. 124, of December 04, 2013, Paragraph 3.86).

PROPER NAMES, TRADEMARKS OR TRADE NAMES

The use of Proper Names, Trademarks or Trade Names in the description and/or in claims is not recommended, since there is a risk that the product or characteristic associated with a brand or similar may be modified during the term of the patent, which may make the sufficiency of disclosure of the invention unfeasible. The use of these terms may be authorized, exceptionally, when it is unavoidable and if they are well known to have a precise meaning. (INPI Resolution No. 124, of December 04, 2013, Paragraph 3.51).

LACK OF SUPPORT VERSUS INSUFFICIENCY OF DISCLOSURE

It should be pointed out that, although an objection of lack of support is an objection relating to the claims, under the terms of article 25 of the IPL, it can often also be considered as an objection of insufficiency of disclosure of the invention, under the terms of article 24 of the IPL (see INPI Resolution No. 124, of December 04, 2013, Paragraph 2.13). In this context, the objection resides in the fact that the application, as disclosed, is insufficient to enable a person skilled in the art to carry out the invention in its entirety, although sufficient with respect to a part of the invention. Both conditions are required to enforce the principle that the wording of a claim must be based on the patent application description. (INPI Resolution No. 124, of December 04, 2013, Paragraph 3.91).

REFERENCE DOCUMENTS

Paragraphs 2.41 to 2.46 of Block I of the INPI Patent Application Examination Guidelines (INPI Resolution No. 124, of December 04, 2013) establish the regulations relating to reference documents.

The documents cited as reference in patent applications may relate to the state of the art or to a part of the disclosure of the invention. Reference to a document (patent or non-patent literature) that relates to the state of the art may be present in the originally filed application or be introduced at a later date (see 2.03).

When the reference document relates to the invention, the examiner will firstly assess whether what is in the reference document is in fact essential for the execution of the invention as understood by article 24 of the IPL:

(a) If not essential, the usual expression "which is incorporated herein by reference", or any expression of the same type, may be retained in the description; and

(b) If the subject matter in the referred document is essential to satisfy the sufficiency of disclosure, the examiner will demand the deletion of the aforementioned expression and the incorporation of the subject matter in the description, as the description of the application must be self-sufficient, that is, capable of being understood in relation to the essential features of the invention, without reference to any other document.

The incorporation of essential subject matter or essential characteristics is, however, subject to the restrictions of article 32 of the IPL, so that:

(a) protection was initially claimed for such characteristics, in order to comply with article 25 of the IPL;

(b) such features contribute to solving the technical problem underlying the invention;

(c) such characteristics clearly belong to the description of the invention contained in the application and, therefore, to the content of the application as filed; and

(d) such characteristics are precisely defined and identifiable within all technical information in the reference document.

If the reference document is essential for the accomplishment of the invention, but was not available to the public on the date of filing of the application, such document will only be accepted as a reference if it has been made available to the public by the date of publication of the application. In the event of this unavailability, the examiner may question the fulfillment of the sufficiency of disclosure of the application based on article 24 of the IPL.

In the exceptional case of a patent application citing a published document that contains essential subject matter for a correct understanding of the invention (but which is not accessible to the examiner), a requirement will be issued for the presentation of the document, under the risk of rejection of the application based on the absence of sufficiency of disclosure.

DEFINITION IN TERMS OF FUNCTION

Paragraphs 3.93 to 3.95 of Block I of the INPI Patent Application Examination Guidelines (INPI Resolution No. 124, of December 04, 2013) establish the regulations relating to the definition of the invention in functional terms.

A claim may broadly define a feature in terms of its function, i.e. as a functional feature, even when only one example of the feature has been given in the description, if the person skilled in the art considers that other means could be used for the same function (see also 3.10 and 3.53).

For example, the expression "terminal position detection means" in a claim may be supported by a single example comprising a limit switch, being evident to the person skilled in the art that a photoelectric cell or strain gauge may also be used. However, if the entire content of the application conveys the impression that a function must be performed in a particular way, without any indication that alternative means are envisaged, and a claim is formulated in such a way as to cover other means, or all means, of performing the function, then such a claim is not admissible due to lack of support. In this case, the description does not support the claim framework when it is limited to stating, in vague terms, that other means can be used if there is no clarity regarding what they can be or how they can be used, thus violating articles 24 and 25 of the IPL. It will therefore be necessary to reformulate the claim in order to restrict it to what was sufficiently described in the description.

DRAWINGS

If the drawings presented do not have quality for visualization, the examiner may issue a requirement, based on the lack of sufficiency of disclosure (Article 24 of the IPL), for the reproduction of the copies of the Drawings, respecting the material originally revealed in the filing (Article 32 of IPL). (INPI Resolution No. 124, of December 04, 2013, Paragraph 4.03).

It should be noted that sufficiency of disclosure, in addition to being one of the necessary conditions for granting a patent, also plays an important role in fulfilling the legal relationship established between the State and the patentee, allowing the content of the patent to be used when it becomes available in the public domain and, within certain limits, after publication of the application. Given these considerations, it is possible to conclude that there may be an invention without sufficient description, but in this situation, the applicant cannot have a patent. Since the lack of sufficiency of disclosure in a patent has as its main negative result a dysfunction of the system, as it would allow the patentee to accumulate two protections simultaneously: patent and industrial secret.

SUFFICIENCY OF DISCLOSURE IN CHEMICAL INVENTIONS

The analysis of compliance with the condition of sufficiency of disclosure in patents in the chemistry field is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraphs 2.13 a 2.19, 3.38 to 3.39 and 3.85 to 3.97 (INPI Resolution No. 124, of December 4, 2013), Block II, Paragraphs 6.9 to 6.14 and 7.7 (INPI Resolution No. 169, of July 15, 2016), and INPI Guidelines for Examination of Patent Applications – Chemistry, Items 3.1, 4.1, 7.1 and 9.1.3 (INPI Resolution No. 208, of December 27, 2017).

COMPOUNDS DEFINED BY MARKUSH FORMULA

The compliance with the sufficiency of disclosure condition in patent applications related to compounds defined by Markush Formula is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 and 3.38 to 3.39 (INPI Resolution No. 124, of December 4, 2013), and Block II, Paragraphs 6.9 to 6.14 (INPI Resolution No. 169, of July 15, 2016).

Markush Formula is a basic chemical structure representation of a group of compounds, which can be replaced by one or more variable substructures, which are accompanied by a list of definitions of these variable portions. Therefore, a multiplicity of compounds may be protected in a patent from a unique representation structure (INPI Guidelines for Examination of Patent Applications, Block II, Paragraphs 6.2 to 6.4).

All possible substituents claimed in the Markush Formula must be clearly and precisely based on the patent application description. Generic and undefined terms, such as “aryl”, “heteroaryl”, “alkyl”, “alkoxyl”, “cycloalkyl”, “inferior alkyl”, “substituted”, etc., are not allowed. Such expressions are imprecise, since they do not define important characteristics of the substituent, such as carbon chain size, number and nature of heteroatoms, presence or absence of branches in the carbon chain, among others.

The condition of sufficiency of disclosure of a group of inventions represented by means of a Markush Formula is only satisfied if the information described in the patent application allows the reproduction of each invention by a person skilled in the art. In the case of compounds defined by a Markush Formula, it cannot be predicted or extrapolated that compounds with substituents

belonging to different chemical classes can be obtained by the same preparation method, since the nature of the reactions involved in the synthesis is different.

Thus, for all compounds defined in a Markush Formula to be considered sufficiently described, the patent application description must fully describe the invention in order to allow a person skilled in the art to carry out the invention without undue experimentation. The patent application description must present detailed information on the reactions and conditions involved in the synthesis processes, including concrete examples of the production of at least one representative compound for each chemical class encompassed in the different substituents provided for in the Formula. In short, the patent application description should present examples that clearly teach how the different substituents foreseen in the Markush Formula can be incorporated into the general basic structure. In cases where the person skilled in the art cannot carry out the invention as claimed, or where this represents an undue effort of experimentation, the generic claims should be restricted to the embodiments mentioned in the patent application description.

SALTS, N-OXIDES, ESTERS AND ETHERS

The compliance with condition of the sufficiency of disclosure in patent applications related to salts, N-oxides, esters and ethers of compounds is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 (INPI Resolution No. 124, of December 4, 2013).

Substantive analysis of patent applications claiming salts, N-oxides, esters and ethers follows the same guidelines applied to chemical compounds in general. For specific information about the examination of this matter, Item 2.4 of the INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208, of December 27, 2017) should be considered.

PRO-DRUGS

The compliance with condition of the sufficiency of disclosure in patent applications related to pro-drugs is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 (INPI Resolution No. 124, of December 4, 2013).

Substantive analysis of patent applications claiming pro-drugs follows the same guidelines applied to chemical compounds in general. For specific information about the examination of this matter, Item 2.5 of the INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208, of December 27, 2017) should be considered.

INTERMEDIATES COMPOUNDS

Intermediates, in the strict sense, are chemical compounds (or groups of chemical compounds) that are used in the production route of another chemical compound (or group of chemical compounds), through chemical(s) and/or physical changes(s), losing their identity.

The claims relating to the intermediate(s) are necessarily chemical compound claims and the substantive analysis of this matter follows the same guidelines applied to chemical compounds in general. For specific information about the examination of this matter, Item 2.6 of the INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208, of December 27, 2017) should be considered.

The compliance with condition of the sufficiency of disclosure in patent applications related to intermediates compounds is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 (INPI Resolution No. 124, of December 4, 2013).

STEREOISOMERS

The compliance with condition of the sufficiency of disclosure in patent applications related to stereoisomers is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 (INPI Resolution No. 124, of December 4, 2013) and INPI Guidelines for Examination of Patent Applications – Chemistry, Items 3.1 and 3.2 (INPI Resolution No. 208, of December 27, 2017).

The clear and sufficient description of the stereoisomer in its pure form resides in the characterization of the absolute configuration of its chiral center at the time of filing the patent application.

Analytical techniques such as circular dichroism (CD), nuclear magnetic resonance (NMR)

(with or without addition of chiral shift reagent), circular birefringence, optical rotatory scattering, chromatography (with chiral column), polarimetry and single crystal X-ray diffraction can be used for the characterization of the claimed enantiomer/atropisomer/diastereoisomer.

The parameters of the process for obtaining the stereoisomer, either by asymmetric synthesis or by the purification process after the synthesis of the compound, must be specified in the description, in order to guarantee its reproducibility by a person skilled in the art.

Due to the possibility of racemization of chiral compounds during the synthesis process, it is important that the description reveals the reagents used (especially in the chiral center formation step), the reaction conditions, and the isolation and purification methods of the stereoisomer obtained by said process. The description must also describe the eventual enantiomeric excess obtained and the analysis method used for its measurement.

Stereoisomers must be defined using the official nomenclature IUPAC or other system that unambiguously identifies them. It is noteworthy that the use of the generic expression “its stereoisomers” in claims referring to a compound *per se* is not sufficient to identify the stereoisomers in a clear and precise way. If the patent description sufficiently describes these subject matter, the claim may be reformulated in order to better define the claimed matter.

POLYMORPHS

The compliance with condition of the sufficiency of disclosure in patent applications related to polymorphs is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 (INPI Resolution No. 124, of December 4, 2013) and INPI Guidelines for Examination of Patent Applications – Chemistry, Item 4.1 (INPI Resolution No. 208, of December 27, 2017).

The identification of a crystalline form is done by means of physical-chemical parameters that define its structure. Crystal definition merely by designations such as, for example, alpha or beta form, form I or II, does not clearly and precisely define the crystalline form.

For an adequate definition and characterization of the crystalline form, the patent application description must contain, on the application filing date, the identification data obtained by physicochemical characterization techniques for solids, such as those exemplified below, or by

validated alternative techniques that better identify it:

a. Single Crystal X-Ray Diffraction (Single Crystal XRD);

b. X-Ray Powder Diffraction (XRPD);

c. Solid State Carbon-13 Nuclear Magnetic Resonance Spectroscopy (^{13}C NMR);

d. Infrared Spectroscopy;

e. Raman Spectroscopy;

f. Electron Microscopy;

g. Thermal Analysis: Differential Scanning Calorimetry (DSC), Thermogravimetry (ATG) and Differential Thermal Analysis (DTA).

It should be noted that the single-crystal XRD analysis is considered to be sufficient for the perfect characterization of the crystal structure of the solid. If single-crystal XRD data are not available, the XRD technique using the powder method with indexing must be used, associated with other methods of physical-chemical characterization of solids, provided that the set of techniques is sufficient for the unambiguous identification of the crystalline form.

It is worth mentioning that more advanced solid characterization techniques not provided for in these Guidelines will be evaluated as to their pertinence for the identification of the claimed crystalline solid. In the absence of crystalline solid characterization data, it will be considered that the patent application description does not clearly and sufficiently describe the claimed subject matter. It should be remembered that the presentation of any characterization data of the claimed solid will not be allowed after the filing of the patent application, as it would be considered an extrapolation of the originally filed subject matter.

The parameters of the process for obtaining the crystalline form must be specified in the patent application description, in order to guarantee its reproducibility by a person skilled in the art. Essential parameters of the preparation process are considered, for example, the type of solvent and its concentration, rates of addition of solvent(s), heating and cooling rates, description of the method of obtaining seeds eventually used in the crystallization process and other parameters that

may be considered critical.

Attention must be draw to the fact that the claimed crystalline form is considered part of the preparation process, that is, for the process to be considered sufficiently described in order to allow its reproduction by a person skilled in the art, the polymorph obtained by such a process must be properly characterized in the patent application description.

SOLVATES, CLATHRATES, CO-CRYSTALS

The compliance with condition of the sufficiency of disclosure in patent applications related to solvates, clathrates, and co-crystals is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 (INPI Resolution No. 124, of December 4, 2013) and INPI Guidelines for Examination of Patent Applications – Chemistry, Item 5 (INPI Resolution No. 208, of December 27, 2017).

In some crystalline solids, the solvent may be incorporated into the compound crystalline network in stoichiometric or non-stoichiometric proportions. These molecular adducts are called solvates, also known as pseudopolymorphs. When the water is the crystallization solvent, the resulting solid is called hydrate. Clathrates are inclusion compounds in which a guest molecule is entrapped in a cavity of the host molecule or the host molecule network (e.g., cyclodextrin inclusion complexes). In general, solvates, clathrates, and co-crystals have the following common characteristics:

1. All of them are formed by at least two molecules;
2. All of them may have different crystalline forms;
3. All of them may have different characteristics according to the structure and constituents of the crystal.

When the invention is any one of these products, the patent application examination should take these elements in consideration:

- For a clear and sufficient description of a solvate, clathrate, crystalline or co-crystal complex, chemical identification of the molecule and stoichiometry is mandatory, which can be determined by using thermogravimetric analysis techniques (ATG), Karl Fischer or other validated techniques that provide such information;
- If the claimed invention is a solvate, the instructions contained in the Chemical Compound Item of INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208, of December 27, 2017), and in the INPI Patent Application Examination Guidelines, Block II (INPI Resolution No. 169, of July 15, 2016) must be consulted;
- If the claimed invention is a crystalline form, it must be physicochemically characterized by the techniques described in the Polymorph Item of INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208, of December 27, 2017), and in the INPI Patent Application Examination Guidelines, Block II (INPI Resolution No. 169, of July 15, 2016);
- The use of the generic expressions "and its solvates", "and its hydrates", "and its clathrates" and/or "and its co-crystals", in claims, referring to a compound *per se* does not identify clearly and precisely the solvates, hydrates, clathrates and co-crystals derivatives and are therefore not accepted.

COMPOSITIONS, FORMULATIONS AND PHYSICAL FORMS OF COMPOSITIONS

The compliance with condition of the sufficiency of disclosure in patent applications related to compositions, formulations and physical forms of compositions is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 (INPI Resolution No. 124, of December 4, 2013), INPI Patent Application Examination Guidelines, Block II, in its Paragraphs 7.1 to 7.15, and INPI Guidelines for Examination of Patent Applications – Chemistry, Item 5 (INPI Resolution No. 208, of December 27, 2017).

A pharmaceutical composition is usually defined by its constituents. However, compositions can still be defined by mixed characteristics, in order to encompass characteristics of physical form or application, provided that they are defined qualitatively and/or quantitatively by their

constituents. Qualitative and/or quantitative definitions must be present in the patent application description to better define the composition of interest. Depending on the invention, quantitative definitions may be essential and, if so, mandatory.

Compositions defined solely by their use, form of administration, or mechanism of action are not precise and therefore not accepted. It is important to note that the new medical use of a pharmaceutical composition already well known for another purpose does not make the known product new. Inventions related to new medical uses of compositions are claimed exclusively through Swiss Formula-type claims.

COMBINATION OF COMPOUNDS

A compound combination is the association of two or more compounds targeting a particular end product. The compound combination may be contained in a single form or in separate forms for simultaneous use.

The compliance with condition of the sufficiency of disclosure in patent applications related to compositions, formulations and physical forms of compositions is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.16 (INPI Resolution No. 124, of December 4, 2013), and in INPI Patent Application Examination Guidelines, Block II (INPI Resolution No. 169, of July 15, 2016), Paragraphs 5.24 to 5.30 and 7.16 to 7.23.

Combination comprising compounds defined by Markush formula

When the invention relates to a new combination of two or more compounds, in which at least one of the compounds is defined by a general formula of the "Markush" type, for example,

> Combination characterized by comprising a compound as defined by the general formula (I) in association with compound A,

Special attention should be paid to the clarity and accuracy of the wording of the claim and the INPI Patent Application Examination Guidelines, Block II (Paragraphs 6.13 and 6.14) should be consulted.

Combinations comprising one or more classes of chemical compounds

The invention relates to a combination comprising one or more groups of compounds defined by their chemical class or by their mechanism of action, for example,

> Pesticidal combination characterized by comprising a pyrethroid compound and an X enzyme inhibitor compound.

Defining the compounds of the pharmaceutical combination by their chemical class or by their mechanism of action in a generic way, without specifying which is(are) the exact compound(s) comprised in the combination, is not sufficient to clearly define the subject matter to be protected and, also, to allow the reproduction of the invention by a person skilled in the art. The patent application must present a sufficient description of the compounds that fall within the classes of compounds according to the invention.

Combinations optionally comprising other active ingredients

Patent applications relating to a new combination may encompass, in addition to the main claim related to the combination, accessory claims such as:

> Combination characterized by comprising compound A and B and, optionally, other active ingredients.

In such situations, special attention should be paid to the clarity and accuracy of the wording of the combination claim, as the mere mention of the term “and optionally other active ingredients” is not sufficient to clearly define the claimed subject matter.

The patent application must contain a sufficient description of the compounds that are classified as other active ingredients according to the invention, in order to allow the reproduction of the claimed subject matter by a person skilled in the art.

Combination in which compounds are in separate forms

In patent applications relating to combinations in which the compounds are in separate forms, the description must present evidence that such combinations are obtainable in the form of a “product for simultaneous application”, even if such product is claimed by means of a kit (Guidelines of Examination of Patent Applications, Block II, Paragraph 7.11).

NEW USE OF A KNOWN SUBSTANCE

The compliance with condition of the sufficiency of disclosure in patent applications related to the New Use of Known Compounds is regulated in INPI Guidelines for Examination of Patent Applications – Chemistry, Item 9.1.3 (INPI Resolution No. 208, of December 27, 2017).

Pharmaceutical inventions related to new uses of a known substance can be protected through Swiss Formula-type claims, such as “use of compound X characterized by being for the manufacture a medicine for the treatment of disease Y”. Claims of the type "use of compound X characterized by being for the treatment of disease Y" correspond to claims directed to a therapeutic method and, therefore, are not considered an invention according to the Brazilian IP Law (IPL).

The new claimed use must be related to the manufacture of a medicine for the treatment of a specific disease. Therefore, the patent application description must clearly and sufficiently describe the new use claimed to comply with condition of the sufficiency of disclosure.

In the event that the patent application seeks protection for a new use of several compounds, for example, the new use of compounds identified in a Markush Formula, only the use of the compounds that was effectively demonstrated in the description will be considered sufficiently described in order to support to the new use claimed.

Although, theoretically, the compounds defined by a particular Markush Formula may have similar activities, it is not possible to extrapolate the new use of a single compound to the range of compounds foreseen in the general formula, unless technical data are presented proving this equivalence of effect.

NEW MEDICAL USE

Inventions for new medical use should refer to the application of a pharmaceutical product already known to produce a medicine to treat or prevent a disease that is different from that for which this product was already used in the state of the art.

In patent applications related to a new medical use, the claims must clearly specify the new disease to be treated by the known medicine. New medical use claims that refer to disorders, syndromes, symptoms or any other generic terms, such as "gastrointestinal disorders", "respiratory syndromes", are not accepted, as they cause uncertainty as to the subject matter to be protected. Moreover, claims that refer to the condition being treated in terms of the mechanism of action, for example, "use of compound X to prepare a medicine to treat a disease Y by selectively occupying a serotonin receptor" or "use of compound X to prepare a serotonin reuptake inhibitor medicine" are also not accepted, as they do not clearly and precisely define the disease that is being treated.

It should also be pointed out that characteristics related to the use of the compound, such as the therapeutic scheme (dosage, route of administration/application, dose interval) and/or group of patients do not add novelty to the known use of the compound for the treatment of a certain pathological condition. For example, if the prior art discloses the "use of compound X to manufacture a medicine to treat disease Y" and the patent application claims the "use of compound X to manufacture a medicine to treat disease Y in diabetic patients", the claimed use is not considered new.

In order to comply with condition of the sufficiency of disclosure, the patent application description must clearly and sufficiently describe the new medical use claimed. Also, the description must present technical data that attest and give support for the new medical use claimed since the date of filing of the patent application. In the absence of proof of the new medical use claimed, it is considered that the essential technical characteristic of the claim is not supported in the description and, therefore, the claimed subject matter is not sufficiently described.

Results from "*in vitro*" tests may provide clues to a new therapeutic use. However, it should be remembered that these data are often not confirmed "*in vivo*", due to pharmacokinetic aspects, among others related to the behavior of the drug within the body. So, it is not always possible to extrapolate the results of the "*in vitro*" tests to a practical therapeutic use, unless additional information is provided by the applicant clearly demonstrates this equivalence of effect. In the case

of studies carried out on animals, it is essential that the adopted models could be extrapolated to humans or animals to be treated. For patent application that seeks protection for a new medical use of compounds defined by a Markush Formula, only the use of compounds that has been effectively demonstrated will be considered fully supported. Although, theoretically, the compounds defined by a particular Markush Formula may have similar activities, it is not possible to extrapolate the new medical use of a single compound to the range of compounds foreseen in the general formula, unless tests are presented proving this equivalence of effect.

In accordance with Paragraph 3.89 of Block I of the Patent Application Examination Guidelines, the burden of proving the support of the claims is on the applicant and, for this purpose, additional evidence is accepted during the substantive examination phase, provided that it is intended exclusively to complement the information already contained in the application as initially filed.

SUFFICIENCY OF DISCLOSURE IN PATENT APPLICATIONS RELATED TO MICROORGANISMS

The compliance with condition of the sufficiency of disclosure in patent applications related to microorganisms is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraph 2.13 to 2.19 (INPI Resolution No. 124, of December 4, 2013) and INPI Guidelines for Examination of Patent Applications in the Field of Biotechnology, Paragraphs 2.2 to 2.2.1.2 (INPI Normative Instruction No. 118, of November 12, 2020).

For most patent applications, the condition of sufficiency of disclosure is met through the provision of information related to the invention in the description, in a clear and precise manner, in order to enable its realization by a person skilled in the art. In other cases where the invention involves microorganisms, the description of the invention in patent applications must be complemented by providing information related to the deposit of biological material in an authorized institution.

Deposit of biological material

When the patent application refers to a product or process involving a biological material and this is essential for the practical realization of the claimed subject matter, which cannot be described in a way that a person skilled in the art can understand and reproduce the matter, the description must be supplemented, until the filing date of the patent application, by depositing the material in an institution authorized by INPI or indicated in an international agreement, or in any of the international filing authorities recognized by the Budapest Treaty. It is considered that the term biological material, in this context, can refer to any material containing genetic information and capable of direct or indirect self-replication.

Representative examples include bacteria, archaea, protozoa, viruses, fungi, algae, seeds, animal and plant cell lines, hybridomas, artificial chromosomes, and other vectors. In some of these cases, and according to the requirements of the chosen depositary center, the host cell that houses these biological materials can be deposited.

Cases in which biological material should be deposited

It is important to note that the obligation to deposit the biological material does not necessarily apply to all and any biological material involved in a particular invention, since, for example, polynucleotides and polypeptides must be described through their nucleotide and amino acid sequence (note: even so, there is no impediment that such materials are additionally deposited).

Regarding microorganisms that have nucleotide sequences different from those found in nature, the modified nucleotide sequence must be presented in the application through the sequence listing, or its name known in the art, or the data of the microorganism deposit. When they are essential to confer the inventive feature, information related to specific promoters, the place of insertion of the heterologous material in the genome, the methodology for obtaining the sample, among other essential characteristics, must also be present in the description, so that a person skilled in the art is able to carry out the invention.

In cases where microorganisms are selected from random mutagenesis and genetic alterations that result in a differentiated effect, it is necessary that such microorganisms have been deposited with an International Depositary Authority and that the data regarding the deposit of the biological material (such as declaration of deposit or name of the institution, number and date of deposit) is part of the patent application. In this way, the biological material will be available at the Depositary Authority and will therefore be considered clear, sufficiently described and reproducible. If the microorganism is not deposited, the patent application will be in disagreement with the condition of sufficiency of disclosure.

When the inventive characteristic obtained by the genetic alteration is achieved only with a specific strain used in the application under examination, it is considered that the microorganism itself is essential for the realization of the invention and, therefore, the deposit of biological material is mandatory. On the other hand, the deposit of biological material is not necessary when the inventive characteristic can be achieved with different strains or species of microorganisms available using the methodology described in the application. Thus, for situations in which well-known organisms are merely transformed to express a new and surprising characteristic, it is sufficient to indicate the organism of interest, expressly relating it to the nucleic acid to be used in this transformation, and ensuring that this nucleic acid be described clearly and precisely.

In cases where the invention does not reside in a microorganism or biological material itself, but in its use, modification or cultivation, and a person skilled in the art is not able to carry out the invention without having the sample referred to in the patent application, the deposit of the microorganism or biological material is also necessary.

Deadlines for biological material deposit

With regard to the original deposit of biological material for patent purposes, Paragraphs 2.17 and 2.18 of the INPI Guidelines for Examination of Patent Applications, Block I, establish that the deposit of biological material must be made until the date of filing the patent application, and that such data must integrate the description.

If there is a Unionist priority claim, the deposit of the biological material must take place before or until the date of the claimed priority, if applicable, that is, if the priority rights apply to the biological material.

When the data supporting the deposit of the biological material are not included in the patent application, and the examiner deems that such data are necessary, a technical requirement must be formulated inviting the applicant to manifest about it. If this requirement is not met, the application must be rejected on the grounds of lack of sufficiency of disclosure.

SUFFICIENCY OF DISCLOSURE OF AI-RELATED APPLICATIONS

In the case of inventions involving AI, much has been discussed about the need to establish specific criteria to guarantee the reproduction of the invention by a person skilled in the art. In this sense, INPI is engaged in a series of activities to discuss aspects related to the technical examination of patent applications in the area of AI. Among the technical cooperation partnerships signed between INPI and other patent offices, the following can be mentioned:

(i) Cooperation initiative between INPI and EPO (European Patent Office) to carry out a comparative analysis of the documental framework used for the process of granting patents in the area of Artificial Intelligence (AI) and Computer Implemented Inventions (CII).

(ii) Exchange of knowledge, between INPI and DKPTO (Denmark Office), in the practice of technical examination in the following topics: Artificial Intelligence (AI) and Computer Implemented Inventions (CII).

(iii) Study within the scope of IP BRICS to evaluate the documental framework used by member countries in technical examination activities related to Artificial Intelligence (AI), assessing whether the guidelines for examination of Computer Implemented Inventions (CII) of the Offices of the BRICS members, if they exist, are sufficient to handle AI-related patent applications. In addition, the technical cooperation project seeks to point out the main topics that the guidelines should cover to address the peculiarities of AI-related inventions.

In all the cooperation projects mentioned, it is evident the importance of putting on the agenda the discussion of sufficiency of disclosure to improve the normative documental framework in order to encompass AI in the Industry 4.0 scenario, as well as to contribute to the technical evaluation of such condition. Throughout the studies carried out by INPI as an integral part of the projects mentioned, the examiners responsible for the technical evaluations pointed out some concepts of interest that should be considered in the documental framework when analyzing the condition of sufficiency of disclosure, such as:

(i) Input X Output Correlation

Regarding the inventions applied to AI, INPI identified that an essential point to be put on the agenda, when revisiting the assessment of the condition of sufficiency of disclosure, is the correlation between the input and output data.

(ii) Database and Data Structure

Another topic of extreme relevance in the context of sufficiency of disclosure is related to the concepts of database and data structure. At first, INPI notes that it is necessary to assess the need to reveal the database, depending on the relevance of the structure for the accomplishment of the invention by a person skilled in the art, that is, when the relationships of the database structure are essential for the accomplishment of the invention, the description must present the main characteristics of the database to meet the condition of sufficiency of disclosure.

(iii) “Black Box”

When evaluating patent applications in the Artificial Intelligence scenario, it became evident the need for a more detailed evaluation of the term “black box”, which can directly influence the accomplishment of the invention by a person skilled in the art. Initially, it is observed that the possibility of an invention using a “black box” without impacting the condition of sufficiency of disclosure is linked to the proposed technical effect. That is, if the technical effect of the invention is not directly associated with the content of the “black box”, such a feature will not be a barrier to the invention. Otherwise, it is inferred that the applicant must provide the necessary elements for the accomplishment of the invention by a person skilled in the art.

(iv) Hyperparameters

Lastly, INPI pointed out the relevance of a technical analysis in two terms frequently used in the context of Artificial Intelligence: Hyperparameters and Parameters. In general, the terms are used interchangeably, but they do not have exactly the same meaning, and may have relevance when dealing with the condition of sufficiency of disclosure.

In this scenario, the importance of the condition of sufficiency of disclosure in the Brazilian patent system is evident, and INPI is in the process of updating the guidelines that will establish an adequate analysis of patent applications using AI. Certainly, the development of sequences of steps to assess the condition of sufficiency of disclosure in AI-related patent applications, as well as the improvement of the Examination Guidelines, are of paramount importance for the standardization/harmonization of this system condition. Such improvements will bring positive impacts, contributing to the reduction of examination time and increasing the quality of the patent system.