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BRPTO/DIRPA Rule #208

DECEMBER 27, 2017

Establishes the Examination Guidelines for Patent Applications in the Field of Chemistry

v. 00 - December 3, 2024

THE EXECUTIVE DIRECTOR IN THE EXERCISE OF PRESIDENCY and the DIRECTOR OF PATENTS, SOFTWARE AND INTEGRATED CIRCUIT TOPOGRAPHIES OF THE BRAZILIAN PATENT AND TRADEMARK OFFICE, in the exercise of their powers, and

WHEREAS it is necessary to complement the general aspects on patentability and formalities, established in the BRPTO's Examination Guidelines for Patent Applications, Blocks I and II, with regard to the particularities of the examination of patent applications in the field of Chemistry;

WHEREAS the holding of a Public Consultation, as well as the analysis of the comments and suggestions submitted by the external public on the subject, is considered;

WHEREAS the need to improve the procedures for processing patent applications, in order to increase efficiency and ensure quality;

WHEREAS the aim is to provide greater transparency to the administrative procedures of the BRPTO's Directorate of Patents, Software, and Integrated Circuit Topographies; and

WHEREAS it is necessary to standardize and update the criteria for analyzing patent applications in the field of Chemistry,

HEREBY RESOLVE AS FOLLOWS

Article 1 To standardize the examination of patent applications in the field of Chemistry, in accordance with the "Examination Guidelines for Patent Applications in the Field of Chemistry", attached to this Rule.

Article 2 The normative effects conferred on the Examination Guidelines for Patent Applications in the fields of Biotechnology and Pharmaceuticals, filed after December 31, 1994, which appear in the written opinion published in the BRPTO's Official Gazette #1648, of August 06, 2002, are hereby repealed.

Article 3 This Rule shall come into force on the date of its publication in the BRPTO's Official Gazette.

Rio de Janeiro, December 27, 2017

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BRAZILIAN PATENT AND TRADEMARK OFFICE

EXAMINATION GUIDELINES FOR PATENT APPLICATIONS

ASPECTS RELATED TO THE EXAMINATION OF PATENT APPLICATIONS IN THE FIELD OF CHEMISTRY

DIRECTORATE FOR PATENTS, SOFTWARE AND INTEGRATED CIRCUIT TOPOGRAPHIES

DIRPA-2017

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1 - Introduction

These Guidelines address the particularities of the examination of patent applications in the field of Chemistry, complementing the general aspects of patentability and formalities found in the BRPTO's Examination Guidelines for Patent Applications, Block 1 (BRPTO/PR's Rule #124/2013 - BRPTO's Official Gazette #2241, of December 17, 2013) and Block II (BRPTO/PR's Rule #169/2016 - BRPTO's Official Gazette #2377, of July 26, 2016). As it is a complement to the BRPTO's Guidelines, they must be read together with the aforementioned Guidelines. In order to help the understanding of the text, the chapters and paragraphs of Blocks I and II are identified throughout the document.

2 - Chemical Compound

2.1 - Novelty and Non-Obviousness

The technical examination of the patentability requirements of patent applications claiming chemical compounds follows the same procedures applicable to products in general and are detailed in Block II of the Examination Guidelines for Patent Applications. It should be noted that, in compound patent applications, in which the composition, formulation, and/or physical form are also claimed, it is considered that the novelty and non-obviousness of the compound will be extended to the composition (Paragraph 7.6 of Block II of the Examination Guidelines for Patent Applications), formulation, and/or physical form (accessory inventions).

2.2 - Clarity and Precision of Claims

The most precise way of claiming a chemical compound is defining it in terms of its chemical structure (general formula), nomenclature (according to IUPAC rules), or with another name that defines it unequivocally. The process for obtaining the compound may characterize it only when it cannot be defined as previously described, as determined, as determined in Paragraphs 3.60 and 3.61 of Block I and in Paragraph 4.17 of Block II of the Examination Guidelines for Patent Applications, provided it meets the patentability requirements.

Claims that define the compound by the process for obtaining it are only possible in extreme cases, where it is not possible to define it otherwise and where the process itself is sufficiently precise to avoid ambiguities as to what is being protected. This is due to the fact that the product resulting from the process includes, for example, the respective by-products, which tend to make the claim unclear as to the subject matter it protects.

Independent claims that define the compound only by its physical, physical-chemical or biological properties are not accepted, as such characteristics alone do not identify the compound in question, compromising the clarity and precision of the claimed subject matter, contrary to Article 25 of Law #9,279/96 (Brazilian Patent Statute). For example, an independent claim of the "Compound characterized by having property Y" type would not be accepted, as the term "compound" is uncertain and could refer to any compound that has property Y.

Likewise, independent claims that define a compound by its application or use, for example, "Compound characterized by being used for X" are not accepted, as the subject matter to be protected remains uncertain, contrary to Article 25 of the Brazilian Patent Statute (Examination Guidelines for Patent Applications, Block II, Paragraph 4.16).

The clarity of a chemical compound claim may also be compromised by the use of generic expressions often employed in order to expand the scope of protection to encompass compound derivatives. This is the case for chemical compound claims that claim, in addition to compounds per se, their stereoisomers, hydrates, solvates, prodrugs, ethers, and esters or other derivatives. These expressions do not clearly and precisely identify the compound derivatives, since they define the derivatives by their chemical class or function. If the specification of the patent application sufficiently describes these objects, the set of claims may be reformulated in order to better define the claimed subject matter.

On the other hand, compound claims that contain generic expressions, such as "pharmaceutically acceptable salts" and "agriculturally acceptable salts", may be accepted since: 1) the compound is responsible for the activity, the salt being a release agent of the active fraction of the compound and; 2) the person skilled in the art is aware of the commonly used salts in their area of expertise.

2.3 - Compounds Defined by Markush-Type Formulas

Claims for compounds defined by a Markush-type formula are examined in accordance with the Examination Guidelines for Patent Applications, Block 1, Paragraphs 3.38 and 3.126 to 3.128, and Block II, Paragraphs 6.1 to 6.14.

2.4 - Salts, N-oxides, Esters, and Ethers

Salts, N-oxide, esters, and ethers of chemical compounds known from the state of the art are usually employed to provide the compound with properties that enable more appropriate conditions for its industrial application, such as solubility, dissolution, stability and adequate organoleptic properties.

The technical analysis of patent applications claiming salts, N-oxides, esters, and ethers follows the same guidelines applied to chemical compounds in general. To be considered novel, the claimed salt/N-oxide/ester/ether must not have been anticipated by the prior art. Where the prior art generally anticipates salts/N-oxides/esters/ethers of known compounds, the claimed salt/N-oxide/ester/ether must not have been specifically disclosed (See Item 2.8 of these Guidelines and the Examination Guidelines for Patent Applications, Block II, Paragraphs 4.16 to 4.25 and 5.31 to 5.34). For example, the patent application claims protection for the mesylate salt of compound A. The prior art document discloses compound A and salts thereof, listing mesylate, fumarate, and hydrochloride as preferred salts. In this case, the mesylate salt of the claimed compound A is considered to be specifically disclosed in the prior art and, therefore, is not novel. On the other hand, if the patent application claims the succinate salt of compound A, said salt will be considered novel, since it was not specifically mentioned among the preferred ones in the prior art document.

If a particular salt, N-oxide, ester, or ether changes the properties of the base compound in an non-obvious manner for one skilled in the art, said salt, N-oxide, ester, or ether is considered endowed with non-obviousness. On the other hand, the description of an alternative salt/N-oxide/ester/ether of a known compound, when disassociated from a non-obvious property or an unexpected technical effect over the state of the art, does not involve non-obviousness.

Normally, the process of obtaining a salt, N-oxide, ether, or ester involves the combination of known and classic procedures in the state of the art, since all the reactions for obtaining these classes of compounds are described in the literature and, therefore, are obvious to a person skilled in the art.

However, if the salt, N-oxide, ether, or ester is considered patentable, the obtaining processes thereof may be analyzed as analogous processes (Item 8 of these Guidelines) and, consequently, will also be endowed with the patentability requirements.

It should be noted that the use of the generic expressions "ethers thereof" and/or "esters thereof" in claims referring to a compound per se, do not clearly and precisely identify the ether and ester derivatives of the compound, as they only define the derivatives through their chemical class or chemical function. If the specification of the patent application sufficiently describes these objects, the set of claims may be reformulated in order to better define the claimed subject matter.

On the other hand, compound claims that contain generic expressions such as "pharmaceutically acceptable salts", "agriculturally acceptable salts", "immunologically acceptable salts", and "N-oxides" may be accepted since: 1) the compound is responsible for the activity, the salt or N-oxide being a release agent of the active fraction of the compound and; 2) the person skilled in the art is aware of the salts commonly used in their area of expertise.

2.5 - Prodrugs

The chemical compounds may act as prodrugs, i.e., compounds that require prior biotransformation to exhibit their pharmacological effects. They may also be considered inactive compounds (or substantially less active than the drug) which, after administration, undergo biotransformation, leading to pharmacologically active compounds.

Prodrugs are generally developed from obtaining derivatives of certain functional groups of a given compound, aiming to optimize the physicochemical, biopharmaceutical or pharmacokinetic properties of pharmacologically active compounds, overcoming eventual barriers related to the drug formulation and delivery, such as low water solubility, chemical instability, insufficient oral absorption, pre-systemic metabolism, inadequate penetration into the central nervous system, toxicity, and local irritation.

The technical analysis of this subject matter follows the same guidelines applied to chemical compounds in general. Especially regarding the analysis of the non-obviousness requirement, it is important to note that, in certain cases, a known strategy to improve the pharmacological or pharmacotechnical properties of drugs may lead to an effect that would not be evident to a person skilled in the art.

It is emphasized that the use of the generic term “prodrugs thereof” in claims referring to a compound per se does not identify the prodrugs of the compound clearly and precisely. If the specification of the patent application sufficiently describes these objects, the set of claims may be reformulated in order to better define the claimed subject matter.

2.6 - Intermediate Reaction 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 and/or physical alteration(s), losing its identity. By way of simplification, reference to "chemical compound" will encompass "group of chemical compounds". In the context of these Guidelines, intermediates may be intermediate compounds per se or starting products (precursors).

Of course, there may be chemical compounds that, in addition to functioning as precursors (intermediates) of a particular chemical compound, also have final applications, such as pesticides, drugs, dyes, etc. However, in this case, that is, when they are performing their function as drugs, etc., they will no longer be "intermediates" in the sense of these Guidelines and must be analyzed according to the previous item.

Bearing in mind the above explanations, two situations may occur:

(1) the intermediate is the main invention;

(2) the intermediate is what is conventionally called an "ancillary invention", in which the main invention may be a final chemical compound or a process for obtaining a chemical compound.

In cases where the intermediate compound is not the main invention, it must be evaluated whether the intermediate and the process for obtaining it belong to the same inventive concept of the main invention, which is a compound (final product) and/or a process for obtaining it. Here, the instructions of the Examination Guidelines for Patent Applications, Block 1 - Paragraphs 3.119 to 3.125 are suitable.

Note that, in both cases, claims regarding the intermediate(s) necessarily are product claims and should be treated as such, applying the most appropriate instructions set out in these Guidelines. Also, in both cases, claims aimed at the process for obtaining the intermediate(s) are accepted.

2.6.1 - Intermediate compounds as main invention

Claims regarding the intermediate(s) are, necessarily, chemical compound claims and the technical analysis of this subject matter follows the same guidelines applied to chemical compounds in general.

The non-obviousness of an intermediate must be judged in terms of its application, as an intermediate, and its differences with regard to the compounds of the prior art. Thus, if the closest prior art reveals compounds similar to the claimed intermediate but does not suggest their application in obtaining other compounds, that is, their application as intermediates, it is understood that it would not be obvious or evident for a person skilled in the art to use compounds similar to those of the prior art as synthesis intermediates.

In the case where the compounds of the closest prior art work as intermediates, the differences between the claimed (intermediate) compound and those of the prior art must be observed, in order to assess whether or not these differences are obvious, considering the intermediate function of the claimed compound.

2.6.2 - Intermediate compounds as an ancillary invention

When the intermediate is an ancillary invention in a patent application relating to another compound as the main invention, it is not possible to extrapolate the novelty and non-obviousness of the main invention to the intermediate, since the effects/activities/purposes of the main invention and of the intermediate are different.

In cases where the intermediate compound is not the main invention, it must be evaluated whether the intermediate and the process for obtaining it belong to the same inventive concept of the main invention, which is a compound (final product) and/or a process for obtaining it. Here, the instructions of the Examination Guidelines for Patent Applications, Block 1 - Paragraphs 3.119 to 3.125 are suitable.

2.6.3 - Process for obtaining intermediate compounds

A process for obtaining an intermediate may constitute the main invention of the patent application, but more commonly it is an ancillary invention to a main invention of a final compound or even an intermediate.

In the first case, in which the process for obtaining the intermediate is the invention, the claims of the process for obtaining the intermediate shall define:

(1) the starting material, the obtained product, and the means for transforming the first into the second and;

(2) the various steps necessary to achieve the proposed object.

2.7 - Chemical Compounds Found in Nature

Chemical compounds found in nature are not considered an invention, in accordance with the provisions of Article 10 (IX) of the Brazilian Patent Statute.

Chemical compounds synthetically obtained that have naturally occurring counterparts not able to be distinguished from compounds found in nature, are also not considered invention. This aspect was addressed in greater detail in the Examination Guidelines for Patent Applications, Block II, Paragraph 1.43, and in the Examination Guidelines for Patent Applications in the Field of Biotechnology, Item 4.2.1.1.

2.8 - Chemical Compounds Selection Patent Applications

Some patent applications may deal with a selection of compounds from a broad class of compounds described in the prior art, such as, for example, compounds defined by generic Markush-type formulas. Usually, the above document refers to a new class of chemical compounds.

The technical examination procedures for chemical compounds selection patent applications are detailed in Block II of the Examination Guidelines for Patent Applications, Paragraphs 4.19 to 4.25 and 5.31 to 5.34.

In general terms, to be considered new, the selected chemical compound must not have been specifically disclosed in the prior art in the form of examples, tests, results, lists, tables, nomenclature, individual structural

formula, or preparation method. Regarding the non-obviousness, the selection of said compound must not be obvious or evident to a person skilled in the art in view of the teachings of the state of the art. Invariably, as it is a selection of compounds already generically described in a previous document, the evaluation of the non-obviousness requirement of the compounds selection patent application involves the submission of comparative data in relation to the state of the art. As defined in Block II of the Examination Guidelines for Patent Applications, Paragraphs 4.19 and 5.32, the comparison must be carried out in relation to the closest prior art, which, in this case, corresponds to the compound(s) with greatest similarity specifically disclosed in the prior art.

The following are some examples that illustrate three situations that may occur in the technical examination of chemical compounds selection patent applications: 1) Selected compounds that are obvious and lack novelty; 2) Novel selected compounds that are obvious, and; 3) Novel and inventive selected compounds.

Example 1: Compounds that are obvious and lack novelty

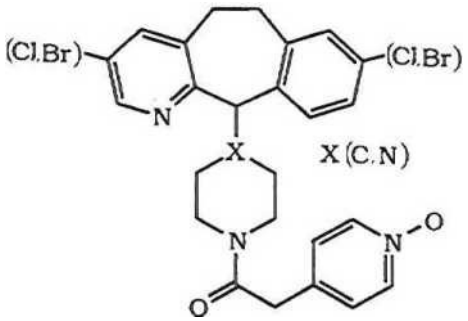
Invention

Tricyclic amide compounds useful in the treatment of proliferative diseases.

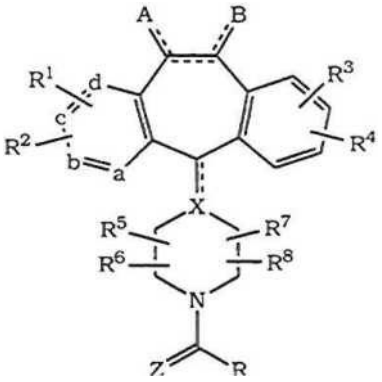
Prior Art

The prior art document discloses tricyclic amide or urea compounds also used in the treatment of proliferative diseases.

Invention



Prior Art



Technical analysis

The selected chemical compounds represent a restricted group among the genericaly disclosed compounds in the Markush formula of the prior art document. These selected compounds in the patent application under analysis do not correspond to the compounds exemplified in the prior art document; however, they were described among the so-called preferred compounds in said document. Thus, the claimed compounds are considered as specifically disclosed in the prior art (Examination Guidelines for Patent Applications, Block II, Paragraphs 4.21 to 4.23) and do not fulfill the novelty requirement.

In order to demonstrate the non-obviousness, the Applicant submitted a variety of biological tests comparing the selected compounds with the compounds of greater structural similarity specifically disclosed in the prior art. However, given that the claimed compounds are not novel, they also do not meet the non-obviousness requirement.

Example 2: Novel compounds, that are obvious

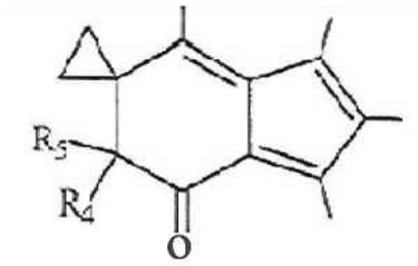
Invention

The patent application relates to iludin analog compounds with antiproliferative activity for the treatment of tumors in mammals.

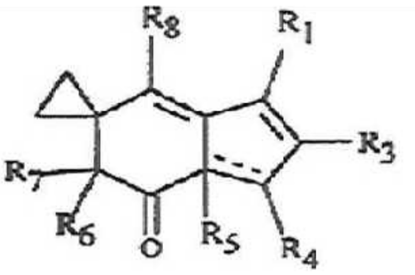
Prior Art

The prior art generally describes, in the Markush formula, iludin analog substances useful as antiproliferative agents.

Invention



Prior Art



Technical analysis

The selected compounds represent a restricted group among the compounds generically disclosed in the prior art document, but as they were not specifically disclosed (Examination Guidelines for Patent Applications, Block II, Paragraphs 4.21 to 4.23), they are considered novel.

The Applicant submitted test results comparing antiproliferative activity between the claimed compounds and the compounds of greater structural similarity specifically disclosed in the prior art. The results presented obvious effects in relation to the prior art, as the antiproliferative activity of the claimed compounds was very similar to that of the compounds disclosed in the prior art (Examination Guidelines for Patent Applications, Block II, Paragraph 5.33). Thus, although the claimed compounds are considered novel, they do not meet the non-obviousness requirement.

Example 3: Novel and non-obvious compounds

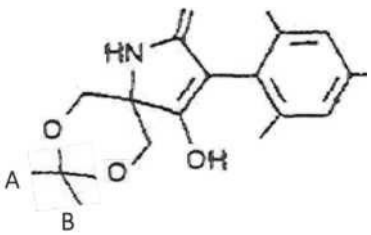
Invention

The patent application relates to phenyl substituted cyclic ketoenols, processes for preparation thereof and use in pesticide and herbicide compositions.

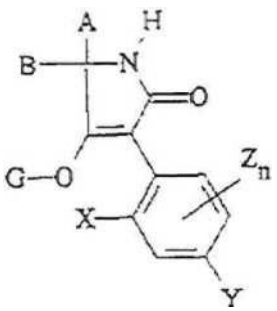
Prior Art

The prior art presents a generic description of cyclic ketoenols with pesticidal and herbicidal activity that encompass the compounds selected in the patent application under analysis.

Invention



Prior Art



Technical Analysis

The compounds claimed in the selection patent application were considered novel because they were not specifically disclosed, although they are chemical derivatives generically provided for in the Markush formula in the prior art document (Examination Guidelines for Patent Applications, Block II, Paragraphs 4.21 to 4.23).

To prove the non-obviousness of the subject matter, test data were submitted that clearly demonstrate the non-obvious technical effect of the claimed compounds compared to the compounds of greater structural

similarity specifically disclosed in the prior art. Thus, the selected compounds were considered non-obvious to a person skilled in the art (Examination Guidelines for Patent Applications, Block II, Paragraph 5.34).

3 - Stereoisomers

Isomers are compounds that have identical molecular formulas but differ in nature, bond sequence, or spatial arrangement of their atoms. Enantiomers, atropisomers, and diastereoisomers, which will be defined below, are members of the class of isomers that have the same molecular formula but differ in the spatial position of their atoms.

Enantiomers are molecules that have a chiral center and are non-overlapping mirror images of each other. Diastereoisomer compounds are stereoisomers that are not mirror images of each other and have different physicochemical properties.

Atropisomer is a subclass of conformational isomers, which may be isolated as a pure chemical species, and which arise from restricted rotation of a single bond (generally due to bulky substituents).

Stereoisomeric mixture is a mixture of stereoisomers, in any ratio. Racemic mixture is an equimolar mixture of stereoisomers.

3.1 - Sufficiency of Disclosure

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

Analytical techniques, such as circular dichroism, nuclear magnetic resonance (with or without addition of chiral displacement reagent), circular birefringence, optical rotational dispersion, chromatography (with chiral column), polarimetry and single crystal X-ray diffraction may be used for 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 subsequent to the compound synthesis, must be detailed in the specification, in order to ensure that a person skilled in the art is able to its reproduce it. Due to the possibility of racemization of chiral compounds during the production process, it is important that the specification discloses the reagents used (mainly in the chiral center formation step), the reaction conditions, the methods of isolation and purification of the stereoisomer obtained by said process. The specification must also describe any enantiomeric excess obtained and the analysis method used for its assessment.

3.2 - Clarity

The stereoisomers should be defined by the official nomenclature (IUPAC) or other system that unequivocally identifies them.

It is emphasized that the use of the generic term “stereoisomers thereof" in claims referring to a compound per se does not identify the stereoisomers of the compound clearly and precisely. If the specification of the patent application sufficiently describes these objects, the set of claims may be reformulated in order to better define the claimed subject matter.

3.3 - Novelty

Stereoisomer compounds will be considered novel if the prior art does not describe the claimed enantiomer/atropisomer/diastereoisomer. Novelty will also be attributed to cases in which enantiomer/atropisomer/diastereoisomer isolated from nature has been described in the prior art and the antipode thereof is now claimed.

However, once the compound in a stereoisomeric mixture has already been disclosed in the prior art such as a racemic mixture, the pure enantiomeric or atropisomeric compounds themselves, are not considered new, since the stereoisomeric mixture already has both stereoisomers. It should be noted that, when the prior art does not specify the absolute configuration of the chiral centers of the described compounds, nor is any chiral influence observed in the synthesis process of such compounds, the enantiomers distribution will be considered as occurring in an equitable manner, that is, it is a racemic mixture.

In the case of patent applications dealing with diastereoisomers, the novelty will be proven when the prior art does not specifically describe the claimed diastereoisomer. In some cases, assessing the novelty of the claimed diastereoisomer is only possible through the submission of characterization data of the known compound so that a comparison can be made between the claimed diastereoisomer and the prior art. In this case, the same analytical techniques employed for the characterization of the claimed diastereoisomer must be applied to samples of the stereoisomer disclosed in the prior art.

The composition containing only one of the stereoisomers is considered novel even though the prior art describes a composition containing the compound in the form of a racemic mixture or other stereoisomeric mixture. In this case, the wording of the composition claim must necessarily exclude the possibility of the protection also falling on the racemic composition or other composition containing stereoisomers already described in the prior art. In particular, the use of the term “consists” limits the constituents of a composition only to those defined in the claim because it is considered a restrictive term (Examination Guidelines for Patent Applications, Block 1, Paragraph 3.48). For example, a claim of the "Composition characterized in that it consists of the R-enantiomer of compound X and vehicles" type excludes any stereoisomer other than that defined in the claimed composition. Note that the term "vehicles" (excipients, adjuvants, carriers, etc.) is related to substances that carry the R-enantiomer and, therefore, does not include the S-enantiomer (even if it is an inactive component). On the other hand, the use of the term “comprises” makes the scope of protection of composition claims wider, compromising novelty. For example, writing a claim of the "Composition characterized in that it comprises the R-enantiomer of compound X and vehicles" type does not limit the constituents only to the elements defined in the claimed composition, and may encompass may encompass other constituents, in addition to the R-stereoisomer, including the S-stereoisomer (Examination Guidelines for Patent Applications, Block 1, Paragraph 3.49). However, a wording of the "Composition characterized in that it comprises the R-enantiomer of compound X and vehicles, where said composition is free of the S-enantiomer of compound X" type could be considered novel, since it excludes the S-enantiomer from the claimed composition.

A composition consisting of a stereoisomeric mixture of defined constitution (determined stereoisomeric excess) will be considered novel, provided that this has not been previously disclosed in the prior art. For example, a claim of the "Composition characterized in that it comprises the R-enantiomer of compound X and vehicles, where the enantiomeric excess is greater than 70%" type could be considered novel.

The use of an isolated enantiomer/atropisomer is not novel if the prior art already discloses the use of its racemic mixture for such purpose. The same is considered for patent applications concerning diastereoisomers of a compound when the prior art anticipates the claimed use of said compound.

If the patent application concerns a new use of an isolated stereoisomer compound, the examination must be based on the Examination Guidelines for Patent Applications, Block 1, Paragraphs 3.73 to 3.76 and Block II, Paragraph 4.18 and the Examination Guidelines for Patent Applications - Chemistry, New Uses of Known Products Item.

3.4 - Non-obviousness

When the purpose of the prior art compound is known, there is an expectation that the pure stereoisomer of this compound will have this same purpose. Thus, it is considered that the person skilled in the art would be motivated to obtain this stereoisomer in order to identify the most suitable form for industrial use, such as, for example, the most active stereoisomeric form. The same reasoning should be applied to the analysis of non-obviousness of compositions containing stereoisomers.

If the patent application concerns a new use of an isolated stereoisomer compound, the examination must be based on the Examination Guidelines for Patent Applications, Block 1, Paragraphs 3.73 to 3.76, and Block II, Paragraph 5.40 to 5.45, and the Examination Guidelines for Patent Applications - Chemistry, New Uses of Known Products Item.

4 - Polymorphs

Polymorphism refers to the ability of a chemical compound to exist in one or more crystalline phases that have different arrangements and/or conformation of molecules in an ordered crystal lattice. Amorphous solids consist of solids with disordered arrangements of molecules, and which do not have a defined crystal lattice.

4.1 - Sufficiency of Disclosure

For the crystalline form characterization, on the patent application filing date, the specification must contain 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 Diffraction by the Powder Method (XRD by the Powder Method);

c. Carbon-13 Nuclear Magnetic Resonance Spectroscopy (13C NMR) in the Solid State;

d. Spectroscopy in the Infrared Region;

e. Raman Spectroscopy;

f. Electron Microscopy;

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

It should be noted that the single-crystal XRD technique is sufficient for the perfect characterization of the crystal structure of the solid. If single-crystal XRD data is not provided, the XRD technique using the powder method with indexing must be used, associated with other methods of physicochemical identification of solids, provided that the set of techniques is sufficient for the unequivocal identification of the crystalline form. It is important to note that more advanced solid characterization techniques not provided for in these Guidelines will be evaluated as to their relevance for the identification of the claimed crystalline solid. In the absence of crystalline solid characterization data, it will be considered that the specification does not describe clearly and sufficiently the subject matter. Note that the submission of characterization data for the claimed solid will not be allowed after filing the patent application, as it would be considered an addition of subject matter.

The parameters of the process for obtaining the crystalline form must be specified in the specification, in order to ensure that a person skilled in the art is able to its reproduce it. Essential parameters in these processes are considered, for example, the indication of solvent(s) and their concentration(s), solvent(s) addition rates, heating and cooling rates, description of the process for obtaining any seeds used in the crystallization process and other parameters that may be considered critical.

It should be noted that the claimed crystalline form is considered part of the preparation process, that is, for the process to be considered sufficiently described, so as to allow its reproduction by a person skilled in the art, the polymorph obtained by such a process must be properly characterized in the specification.

4.2 - Clarity and Precision of Claims

The identification of a crystalline form is done through physical-chemical parameters that define its structure. The simple denomination by designations such as, for example, alpha or beta form, form I or II, does not clearly and precisely define the crystalline form. The following are examples of claims for crystalline forms with clear

and precise wording.

Example 1:

Crystalline form of compound X characterized by having a melting point of 151 °C, measured by differential scanning calorimetry (DSC 2 K min-1); presenting reflections (2-theta) at 7.5, 10.1, 12.0, 12.4, 13.7, 15.0, 16.0, 17.3, 17.7, 18.0, 19.2, 19.8, 20.7, 21.0, 22.2, 22.7, 22.9, 23.6, 24.1, 25.6, and 30.5, with their respective relative intensities

11.4, 63.0, 19.0, 21.0, 7.6, 15.2, 9.5, 7.6, 5.7, 14.3, 5.7, 23.0, 11.4, 11.4, 61.0, 100.0, 13.3, 7.6, 28.6, 9.5, and 7.6, in their X-ray diffractogram; presenting maximum peaks at 3338, 1708, and 1431 cm-1 in its infrared spectrum, presenting maximum peaks at 107.9, 118.2, and 135.0 ppm in its solid state 13C NMR spectrum, and presenting maximum peaks at 3080, 1580, and 122 cm-1 in its Raman spectrum.

Example 2:

Crystalline form of compound X characterized by having reflections (2-theta) at 7.5, 10.1, 12.0, 12.4, 13.7, 15.0, 16.0, 17.3, 17.7, 18.0, 19.2, 19.8, 20.7, 21.0, 22.2, 22.7, 22.9, 23.6, 24.1, 25.6, and 30.5 with the respective relative intensities 11.4, 63.0, 19.0, 21.0, 7.6, 15.2, 9.5, 7.6, 5.7, 14.3, 5.7, 23.0, 11.4, 11.4, 61.0, 100.0, 13.3, 7.6, 28.6, 9.5, and 7.6, in its single-crystal X-ray diffractogram.

4.3 - Novelty

Distinctive characteristics of crystalline forms are based on physicochemical parameters. In general, the closest prior art is the one that discloses the obtaining of the compound that, for the most part, is not characterized in terms of its crystalline structure. In these cases, for the purpose of evaluation of novelty of the claimed crystalline form, physical-chemical characterization data of the solid compound described in the state of the art should be presented at the moment of the patent application filing or in the course of the technical examination.

If the prior art already discloses the claimed crystalline form, even if mixed with other forms, regardless of its concentration, the claimed crystalline form is not considered novel.

The physicochemical characterization data of the prior art compound is unnecessary when the prior art describes the compound in a non-solid state (for example, liquid, pasty or oily) since there is no doubt as to the novelty of the claimed polymorph in these circumstances.

4.4 - Non-obviousness

Although it is the same chemical substance and the possibility of forming different crystal lattices is a peculiar property of solids, polymorphic forms may have different physical-chemical properties in both the product preparation processes and the shelf life, or also in terms of chemical effects.

However, it is important to note that the search for crystalline solids from a compound is common practice in the industry to enhance the physical and chemical characteristics of compounds in general. Thus, the simple characterization of an alternate crystalline solid of a known compound, when disassociated from a non-obvious property of the solid or a technical advance over the state of the art, is obvious.

5 - Solvates, Clathrates, Co-Crystals

In some crystalline solids, the solvent may be incorporated into the crystal lattice of the compound in stoichiometric or non-stoichiometric proportions. These molecular adducts are called solvates, also called pseudopolymorphs. When water is the crystallization solvent, the resulting solid is called hydrate.

When a solvate loses the solvent molecules incorporated into the crystal lattice (intentionally or not) and the crystal retains the solvate's structure, the obtained solid is called a desolvate. This subject matter must be

evaluated as discussed in the Polymorphs item of these Guidelines, as it refers to the crystalline form composed of only one type of molecule.

In turn, clathrates are inclusion compounds in which a molecule (guest) is trapped in a cavity of the host molecule or host molecule network (for example, cyclodextrin inclusion complexes).

In general, echo-crystal clathrates and solvates have the following characteristics in common:

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

In a patent application whose invention is any of these products, it must be considered that:

1) 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 may be determined using thermogravimetric analysis (ATG), Karl Fischer or other validated techniques that provide such information;
2) if the invention to be protected is a solvate, the item on Chemical Compound of these Guidelines and the Examination Guidelines for Patent Applications of the BRPTO should be consulted for evaluation of the claimed subject matter, since the solvate is considered a chemical compound different from the unsolvated or anhydrous corresponding thereof;
3) if the invention to be protected is a crystalline form (clathrate, co-crystal or crystalline form of the solvate), it must be physicochemically characterized using the techniques described in the Polymorphs item of these Guidelines, in addition to the Examination Guidelines for Patent Applications of the BRPTO, in order to define both the constituents and the structure of the crystalline form.
4) the use of the generic expressions "solvates thereof", "hydrates thereof", "clathrates thereof", and/or "co-crystals thereof" in claims referring to a compound per se does not clearly and precisely identify the solvate, hydrate, clathrate, and co-crystal derivatives of the compound. If the specification of the patent application sufficiently describes these objects, the set of claims may be reformulated in order to better define the claimed subject matter.

6 - Compositions, Formulations, and Physical Forms of Compositions

Claims of compositions, formulations, and physical forms of compositions are examined in accordance with the Examination Guidelines for Patent Applications, Block II, Paragraphs 7.1 to 7.15.

6.1 - Clarity and Precision of Claims

As discussed in the Examination Guidelines for Patent Applications, Block II, Paragraphs 7.1 to 7.15, a composition is usually defined only by its constituents. However, the compositions may be further defined by mixed characteristics, in order to encompass characteristics of physical form or application, as long as they are defined qualitatively and/or quantitatively by their constituents. The following are complementary examples of compositions, with emphasis on the clarity and precision assessment of the claims (Article 25 of the Brazilian Patent Statute).

Example 1:

Claim 1: Pharmaceutical composition, characterized in that it comprises compound A and excipients B and C.

Claim 2: Pharmaceutical composition, according to claim 1, characterized in that it is for oral administration.

It complies with Article 25 of the Brazilian Patent Statute, since the composition is defined by its constituents in claim 1 and the administration form is an additional feature that restricts the claimed subject matter to the field of compositions for oral use (tablets, capsules, syrups, etc.).

Claim 3: Pharmaceutical composition, according to claim 1, characterized in that it is in the form of a capsule.

It complies with Article 25 of the Brazilian Patent Statute, since the composition is defined by its constituents in claim 1 and the expression "it is in the form of a capsule" is an additional feature of the claimed subject matter.

Claim 4: Pharmaceutical composition, according to claim 1, characterized in that it is for the treatment of asthma.

It complies with Article 25 of the Brazilian Patent Statute, since the composition is defined by its constituents in claim 1 and its application is an additional feature, which restricts the claimed subject matter to the field of products useful for the treatment of asthma.

Claim 5: Pharmaceutical composition, according to claim 1, characterized in that it releases eighty percent (80%) of component A in less than thirty minutes.

It complies with Article 25 of the Brazilian Patent Statute, since the composition is defined by its constituents in claim 1 and releasing component A is an additional feature informing the properties of the claimed subject matter.

Example 2:

Claim 1: Pharmaceutical composition characterized in that it comprises compound A and excipients B and C for oral administration.

It complies with Article 25 of the Brazilian Patent Statute, since the composition is defined by its constituents. The information on the administration form is an additional feature, which restricts the claimed subject matter to the field of compositions for oral use (tablets, capsules, syrups, etc.).

Example 3:

Claim 1: Pharmaceutical composition for oral administration characterized in that it comprises compound A and excipients B and C.

It complies with Article 25 of the Brazilian Patent Statute, as the composition is defined by its constituents. The information on the form of administration is an additional feature, which restricts the claimed subject matter to the field of compositions for oral use (tablets, capsules, syrups, etc.).

Example 4:

Claim 1: Pharmaceutical composition characterized in that it comprises compound A and excipients B and C for treating asthma.

It complies with Article 25 of the Brazilian Patent Statute, since the composition is defined by its constituents. The information on the composition use represents only an additional feature of the composition, which restricts the claimed subject matter to the field of products useful for the treatment of asthma.

Example 5:

Claim 1: Pharmaceutical composition comprising compound A and excipients B and C characterized in that it is for the treatment of disease Y.

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), as the composition is not characterized by its constituents but by its application. In this case, in order to comply with Article 25 of the Brazilian Patent Statute, it is possible to reformulate the wording of the claim, moving the constituent elements of the composition to the characterizing part. (Examination Guidelines for Patent Applications, Block I, Paragraphs 3.04 to 3.09).

If the composition is known from the state of the art, the claim is not novel either, as the characteristic related

to the use of the composition does not confer novelty to the product.

Example 6:

Claim 1: Composition characterized in that it releases eighty percent (80%) of the active ingredient in less than thirty minutes.

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), as the composition is not characterized by its constituents. The released percentage of active ingredient does not define the claimed subject matter.

Example 7:

Claim 1: Insecticidal composition characterized in that it is in the form of a spray.

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), as the composition is not characterized by its constituents, and the form of application does not define the claimed subject matter.

Example 8:

Claim 1: Pharmaceutical composition characterized in that it comprises compound A and its excipients B and C to be used in the form of prolonged release tablets capable of releasing eighty percent (80%) of component A in less than thirty minutes.

It complies with Article 25 of the Brazilian Patent Statute as the composition is characterized by its constituents, and the pharmaceutical form and product properties are additional characteristics of the composition.

Example 9:

Claim 1: Tablet characterized in that it comprises compound A and excipients B and C.

It complies with Article 25 of the Brazilian Patent Statute, as the tablet is characterized by its constituents (in this case, the composition elements that constitute the invention).

Example 10:

Claim 1: Pharmaceutical form characterized in that it is in the form of a tablet consisting of 100 mg of A, 220 mg of B, and 200 mg of C.

It complies with Article 25 of the Brazilian Patent Statute as the pharmaceutical form is characterized by its constituents and the physical form of a tablet.

Example 11:

Claim 1: Pharmaceutical composition characterized in that it comprises compound A and excipients B and C thereof.

Claim 2: Pharmaceutical composition, according to claim 1, characterized in that the dosage of A ranges from 45 to 90 mg per kg of the patient.

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), as the additional feature of the dependent claim refers to the method of administering the pharmaceutical composition, which is part of a therapeutic regimen and is unrelated to the product. The added feature does not add information on the product per se, generating inconsistency in the claimed subject matter.

Claim 3: Pharmaceutical composition, according to claim 1, characterized in that it is administered twice a day.

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), as the additional feature of the dependent claim refers to the method of administering the pharmaceutical composition, which is part of a therapeutic regimen, and not of a product. The added feature does not add information on the product per se, generating inconsistency in the claimed subject matter.

Example 12:

Claim 1: Composition characterized in that it comprises a compound A and a compound B.

Claim 2: Composition according to claim 1, characterized in that it optionally comprises other active ingredients.

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), as the term "and optionally other active ingredients" does not define said active ingredients.

If the specification of the application sufficiently describes the so-called "active ingredients", the set of claims may be reformulated, in order to restrict the active ingredients to those described in the specification.

Example 13:

Claim 1: Gray soda-lime glass composition characterized in that it comprises an element A and an element B at concentrations x and y, respectively, as coloring agents, the glass having a total light transmission of < 20% for a glass with a thickness of 4 mm.

Claim 2: Gray soda-lime glass composition, according to claim 1, characterized in that the glass has a total light transmission of < 10% for a glass with a thickness of 4 mm.

It complies with Article 25 of the Brazilian Patent Statute, as the composition is characterized by its constituents and respective concentrations thereof. The light transmission (physical parameter) is an additional characteristic of the claimed subject matter.

Example 14:

Claim 1: Fertilizer composition characterized in that it comprises raw material A (for example, ammonium nitrate) and raw material B (for example, calcium sulfate), in concentrations X and Y, respectively.

Claim 2: Fertilizer composition, according to claim 1, characterized in that it contains nutrient Z (for example, total nitrogen) at a concentration of 80% by weight, and nutrient W (for example, calcium) at a concentration of 10% by weight.

It complies with Article 25 of the Brazilian Patent Statute, as the composition is characterized by its raw materials and concentrations thereof. Nutrients and concentrations thereof are additional characteristics of the composition.

Example 15:

Claim 1: Fertilizer composition characterized by consisting of elements X, Y, and Z (for example, carbon, hydrogen, nitrogen, phosphorus, potassium...).

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), as the composition is not characterized by the raw materials that contain such elements, as well as it does not specify the concentrations thereof.

7 - Combinations of Chemical Compounds

A combination is the association of two or more compounds aiming at a certain final product. The combination may be contained in a single form or in separate forms for simultaneous application. For the examination of combinations, Paragraphs 5.24 to 5.30 and 7.16 to 7.23 of the Examination Guidelines for Patent Applications, Block II, must be considered.

In the particular case of inventions related to combinations, the interaction between the associated compounds should produce a non-obvious effect, such as, for example, a synergistic or supra-additive effect, which does not correspond to an additive effect, i.e., the sum of individual effects of each compound that makes up said combination.

Therefore, when the result of the association of two or more known compounds is a sum of the effects that would be expected for each compound used alone, the claimed combination will be considered obvious, since said combination corresponds to a predictable association of known compounds to generate an expected technical effect.

Proof of the non-obvious effect of a combination often involves the presentation of data that allows a comparison between the effects observed with the respective compounds when used alone and those obtained from the combination of these compounds under the same experimental conditions.

Note that the alleged non-obvious effect must not be suggested in the state of the art, for example, in combinations of compounds that belong to the same class of those under analysis (Examination Guidelines for Patent Applications, Block II, Paragraph 7.19).

7.1 - Sufficiency of Disclosure, Clarity and Precision of Claims

7.1.1 - 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 in that it comprises a compound as defined by the general formula (1) in association with compound A", special attention should be given to the clarity and precision of the claim wording and the Examination Guidelines for Patent Applications, Block II (Paragraphs 6.13 and 6.14).

7.1.2 - 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, "Pesticide combination characterized in that it comprises a pyrethroid compound and an enzyme X inhibitor compound".

Defining the combination compounds 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, contrary to the provisions of Article 25 of the Brazilian Patent Statute.

If the specification of the patent application sufficiently describes the compounds that fall within the classes of compounds according to the invention, the set of claims may be reformulated in order to restrict the compounds to those described in the specification.

7.1.3 - Combinations that optionally comprise other active ingredients

Patent applications related to a new combination may encompass, in addition to the main claim related to the combination, ancillary claims of the type:

"Combination characterized in that it comprises compound A and B and, optionally, other active ingredients".

In such cases, it is important to observe that the clarity and precision of the wording of the combination claim, as the simple mention of the term "and, optionally, other active ingredients", is not sufficient to clearly define the claimed subject matter, contrary to the provisions in Article 25 of the Brazilian Patent Statute.

If the specification of the patent application sufficiently describes the compounds that are classified as the other active ingredients according to the invention, the set of claims may be reformulated, in order to better define the subject matter to be protected.

7.1.4 - Combination where the compounds are in separate forms

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

Example:

Specification:

The patent application relates to a combination comprising herbicides A and B. In the specification, the synergistic effect of the combination was demonstrated when the compounds were applied to plants separately, but simultaneously.

Set of Claims:

Claim 1: "Synergistic herbicide combination characterized in that it comprises compound A and compound B."

Claim 2: "Method for weed control characterized in that the plants are treated with the combination as defined in claim 1."

Claim 3: "Method, according to claim 2, characterized in that compound A and compound B are simultaneously or sequentially applied."

Technical analysis:

Claims 1 and 2 may be accepted as long as they meet the patentability requirements. On the contrary, claim 3 may not be accepted, as it includes the possibility of sequentially applying compounds A and B. Since a combination refers to a product from the association of two or more compounds for simultaneous application, the possibility of sequential application is inconsistent with the subject matter to be protected.

8 - Analogous Processes

Analogous processes comprise starting materials and/or final products that present novelty and non-obviousness in light of the state of the art, although such processes involve the combination or use of procedures known from the state of the art.

By identifying novelty and non-obviousness for the starting materials and/or final products, it is not necessary to investigate such requirements for their respective claims of analogous processes, provided that they are linked to the main claim of starting material and/or final product.

In this way, the claims of analogous processes may be generically interpreted as ancillary claims, since, by definition, the attribution of novelty and non-obviousness is a function of the presence of these requirements in the product and/or starting material. In addition to the analogous processes referring to the synthesis of chemical compounds that have novelty and non-obviousness, the concept may also be extrapolated to those processes referring to the production of pharmaceutical, agrochemical, medicaments, catalysts, lubricants, pesticides, or herbicides, among others.

If the technical examination considers that the starting materials and/or final products have no novelty and/or are obvious, the claimed analogous processes will not be accepted for lack of novelty and/or non-obviousness in light of the state of the art.

In another situation, if the technical examination considers that the starting materials and/or final products have no novelty and/or are obvious, but that the claimed processes involve new and/or inventive steps, such process claims must be examined as common process claims, that is, they will no longer be an analogous process claim.

Because the steps involved in analogous processes are generally well known to a person skilled in the art, it may suffice to generically mention them in the specification.

9 - New Uses of Known Products

This item deals with particularities of the technical examination of inventions for new uses of known products, especially new medical uses, in addition to the Examination Guidelines for Patent Applications, Block 1, Paragraphs 3.73 to 3.76 and Block II, Paragraphs 4.18 and 5.40 to 5.45.

The protection of the new use claim refers to the use of a known substance for a new purpose. Thus, the specification must clearly and sufficiently describe the claimed new use.

In the event that the patent application seeks protection for a new use of several compounds, for example, identified in a "Markush formula", only the use of the compounds that was effectively demonstrated in the specification will be considered sufficiently described in order to prove the claimed use. Although, theoretically, the compounds defined by a given "Markush formula" may have similar activities, it is not possible to extrapolate the new use of a single compound to all others, unless tests are presented proving this equivalence of effect.

The patent application regarding a new use of a group of compounds will have unity of invention if said compounds are structurally related (Markush formula, for example) or present the same mechanism of action. In the pharmaceutical area, the patent application relating to a new medical use intended for a set of diseases of the same etiology will also have a unit of invention.

9.1 - New Medical Use

9.1.1 - Novelty

To be considered novel, the new medical use invention must disclose the employment of a known pharmaceutical product to produce a medicament for treating or preventing a disease different from that for which this product was already employed in the state of the art.

Characteristics related to the compound use, such as the therapeutic regimen (dosage, route of administration/application, dosage range) and/or group of patients do not confer novelty to the known use of the compound. For example, if the prior art discloses the “use of compound X to manufacture a medicament for treating disease Y” and the patent application claims the “use of compound X to manufacture a medicament for treating disease Y in diabetic patients”, the claimed use is not considered novel.

9.1.2 - Non-obviousness

In the case of inventions related to new medical use, some aspects should be observed to assess the non-obviousness requirement:

1. The mechanism of action of the compound involved in the new use should not be inferred from its mechanism of action for a medical use already disclosed in the prior art.
2. The new use must refer to the treatment of a disease whose etiology is different from the etiology of the disease related to the use disclosed in the prior art.
3. The new use must not be inferred from the drug structure-activity relationship compared to structurally related molecules, namely, from the structural analogy with other compounds having same activity as the presently claimed one, already disclosed in the prior art.
4. The new use must not be inferred from the disclosure of adverse effects known from the state of the art for the drug in question.
5. The new use must not be inferred from the use of the compound for treating a symptom of a disease already disclosed in the prior art, even though the claimed use concerns a different disease.

9.1.3 - Sufficiency of disclosure of the specification and grounding of the claims

It must be understood that the protection of the new medical use claim is given to the whole use of the known substance to manufacture a medicament for a new therapeutic use. Thus, the specification must clearly and sufficiently describe the claimed new use.

The specification must present evidence that proves the new claimed use at the time of filling. In the absence of evidence of this use, it is considered that the claim essential technical characteristic is not supported by the specification and, therefore, the subject matter does not present sufficiency of disclosure. “In vitro” test results may show signs of a new therapeutic use, however, they are often not confirmed “in vivo”, on the occasion of pharmacokinetic aspects, among others, related to the drug behavior within the body. Thus, it is not always possible to extrapolate "in vitro" test results for an actual therapeutic application, unless additional information is provided proving this equivalence of effect. When regarding studies carried out on animals, the models used must present the possibility of extrapolation to humans or animals to be treated.

In the event that the patent application seeks protection for a new medical use of compounds defined by the "Markush formula", only the effectively demonstrated use of compounds will be considered grounded. Although, theoretically, compounds defined by a given "Markush formula" may have similar applications, it is not possible to extrapolate the use of a single compound to all others, unless evidence is presented to prove this equivalence of effect.

According to Paragraph 3.89, Block I of the Examination Guidelines for Patent Applications, the burden of proving the support of the claims is on the Applicant and, for that purpose, additional evidence is accepted during the technical examination, provided that they are intended exclusively to complement the information already contained in the patent application as initially filed.

9.1.4 - Clarity and precision of claims

New use claims to prepare a medicament must specify the disease being treated. New use claims which refer to disorders, syndromes, symptoms or any other generic terms, for example, “gastrointestinal disorders”, “respiratory syndromes”, will not be accepted, as the subject matter to be protected remains uncertain.

New medical use claims that refer to the condition being treated in terms of the mechanism of action, for example, "use of compound X to prepare a medicament to treat a disease by selective occupancy of a serotonin receptor" or "use of compound X to prepare a serotonin reuptake inhibitor medicament", will not be accepted, as they do not clearly and precisely define the disease in question.

The parts of the claims for new medical uses related to the therapeutic regimen and patient group do not define the use of a compound for preparing a medicament and, therefore, they are not accepted as the subject matter remains uncertain. The following are complementary examples related to the new medical use.

Example 1:

Claim: "Use of product (or compound or active ingredient) X, characterized in that it is to prepare a medicament to treat disease Y.”

It complies with Article 25 of the Brazilian Patent Statute, as the product use is clearly and precisely characterized for the preparation of a medicament to treat a defined disease.

Example 2:

Claim: "Product X characterized in that it is used as a medicament."

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute) since the product is being defined by its use and not by its technical characteristics.

Furthermore, since the product is known from the state of the art, it is not novel (Examination Guidelines for Patent Applications, Block I, paragraph 3. 74).

Example 3:

Claim: "Product X characterized in that it is for the treatment of disease Y."

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute) since the product is being defined by its use and not by its technical characteristics.

Furthermore, since the product is known from the state of the art, it is not novel (Examination Guidelines for

Patent Applications, Block 1, paragraph 3.74).

Example 4:

Claim: "Use of product X characterized in that it is for the treatment of disease Y."

It is not acceptable, since, as worded, it refers to a therapeutic method (Examination Guidelines for Patent Applications, Block I, paragraph 3.76).

Example 5:

Claim: "Process for treating disease Y characterized by the administration of product X."

It is not acceptable since, as worded, it refers to a therapeutic method (Examination Guidelines for Patent Applications, Block I, paragraph 3.76).

Example 6:

Claim: "Use of compound X to prepare a Y receptor inhibitor medicament."

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), as it refers to the condition to be treated in terms of the mechanism of action and does not clearly and precisely define a disease.

Example 7:

Claim: "Use of compound X to prepare a medicament to treat CNS disorders or syndromes."

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), as it refers to the condition to be treated in generic terms and does not clearly and precisely define a disease.

Example 8:

Claim: "Use of product X characterized by being in the preparation of a drug to treat disease Y, which consists of orally administering the medicament 3 times a day."

It is not acceptable for lack of clarity (Article 25 of the Brazilian Patent Statute), since the additional feature of the claim ("...consists of orally administering the medicament 3 times a day") is inconsistent with the claimed subject matter, as it refers to the method of administration (part of a therapeutic regimen) and not to the use (process to prepare a medicament to treat disease Y).

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