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Examination Guidelines for Patent Applications

The Chemistry Field

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Summary

MINISTRY OF INDUSTRY, FOREIGN TRADE AND SERVICES

BRAZILIAN PATENT AND TRADEMARK OFFICE – BRPTO

GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS

Aspects related to the examination of patent applications in the chemistry area

Patent board, computer programs and topographies of integrated circuits

DIRPA-2017

1 Introduction

These Guidelines address the particularities of the examination of patent applications in the chemistry area, complementing the general aspects on patentability and formal procedures found in the Guidelines for the Examination of Patent Applications issued by the BRPTO, Block I (Rule BRPTO/PR #124/2013 – Official gazette #2241, of December 17, 2013) and Block II (Rule BRPTO/PR #169/2016 – Official gazette #2377, of July 26, 2016). Because this is supplementary to the BRPTO Guidelines, they must be read in conjunction to said Guidelines. Seeking to help to understand the text, 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 follow the same procedures applicable to products in general and are detailed in the Block II of the Guidelines for the Examination of Patent Applications. It should be noted, however, that in compound patent applications, in which a composition, formulation and/or physical form are also claimed, it is considered that the novelty and non-obviousness of the compound will be valid for the composition (paragraph 7.6 of Block II of the Guidelines for the Examination of Patent Applications), the formulation and/or physical form (ancillary inventions).

2.2 Clarity and precision of the claims

The most precise form to claim a chemical compound is by defining it in terms of its chemical structure (general formula), nomenclature (as per IUPAC rules) or other name that may define it unambiguously. Only in cases where it cannot be defined as described above, the compound may be characterized by its process of obtaining, as established in paragraphs 3.60 and 3.61 of Block I and paragraph 4.17 of Block II of Patent Applications the Guidelines for the Examination of Patent Applications provided it meets the patentability requirements.

Claims that define the compound by its respective process for obtaining are only possible in extreme cases, when it is not possible to define said compound in any other way and when the process itself is sufficiently precise so as to avoid ambiguity as to the subject matter sought to be protected. This is because, as far as the product resulting from the process includes, for instance, the respective byproducts, such claims tend not to be clear with regard to the matter which they protect.

Independent claims defining the compound only by its physical, physical-chemical or biological properties are not acceptable because these features alone, do not identify the compound in question, thus compromising the clarity and precision of the claimed matter, which is contrary to the provisions of Article 25 of the Brazilian Patent Statute (Law #9,279/96). For example, an independent claim directed to a “Compound characterized by having the property Y” would not be accepted, since the term “compound” is undefined and can refer to any compound which have the property Y.

Similarly, independent claims that define a compound by its application or use, such as, for example, “A compound characterized by being used for X” are **not** accepted, as they cause indefiniteness to the matter to be protected, which is at variance with the provisions of Article 25 of the Brazilian Patent Statute (under the Guidelines for Examination of Patent Applications, Block II, paragraph 4.16).

The clarity of a chemical compound claim may also be compromised by the use of general expressions often employed in order to expand the scope of protection to encompass derivatives of the compound. This is the case of chemical compound claims which claim in addition to the compounds per se, their stereoisomers,

hydrates, solvates, prodrugs, ethers and esters or other derivatives. These expressions do not identify the derivatives of the compound clearly and precisely, since only define the derivatives by means of their chemical class or function. If the patent application sufficiently describes these objects, the claim chart can be reformulated in order to better define the claimed subject matter.

On the other hand, the compound claims containing generic expressions, such as "pharmaceutically acceptable salts" and "agriculturally acceptable salts" can 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 routinely employed salts in his/her area of expertise.

2.3 Compounds defined by markush formulas

Claims directed to compounds defined by Markush formulas are examined according to the Guidelines for Examination of Patent Applications, Block I, 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-oxides, esters and ethers of chemical compounds known from the prior art are usually employed to provide the compound properties that enable more appropriate conditions for their industrial application as, for example, solubility, dissolution, stability and suitable organoleptic properties.

The technical analysis of patent applications claiming salts, N-oxides, esters and ethers follows the same guidelines applied to chemicals in general. To be considered novel, the salt/N-oxide/ester/ether claimed may not have been anticipated in the art. When the state of the art generically anticipates salts/N-oxides/ethers/esters of compounds known in the art, the claimed salt/N-oxide/ether/ester may not be specifically disclosed (see item 2.8 herein and the Guidelines for the Examination of Patent Applications, Block II, paragraphs 4.16 to 4.25 and 5.31 to 5.34). For example, the patent application is claiming protection for the mesylate salt of compound A. The prior art discloses compound A and salts thereof, including mesylate, fumarate and hydrochloride as preferred salts. In this case, the mesylate salt of the claimed compound A is considered specifically disclosed in the prior art and therefore does not exhibit novelty. On the other hand, if the patent application seeks protection for the succinate salt of compound A, said salt will be considered novel, since it was not specifically mentioned among the preferred compounds of the cited prior art document.

If a particular salt, N-oxide, ester or ether change the properties of the basic compound in an non-obvious way for a person skilled in the art, said salt, N-oxide, ester or ether is considered endowed with inventiveness. On the other hand, the mere description of an alternative salt/N-oxide/ester/ether to a known compound, when disassociated from a non-obvious property or an unexpected technical effect over the prior art, is obvious.

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

However, if the salt, N-oxide, ether or ester is considered patentable, the processes for obtaining them can be analyzed as analogous processes (Item 8 of these Guidelines) and, therefore, will also fulfill the patentability requirements.

It is emphasized that the use of generic terms "ethers thereof" and/or "esters thereof" in the claims referring to a compound per se does not identify the ethers and esters derivatives of the compound clearly and precisely, since they only define derivatives through their chemical class or function. If the specification of the patent application sufficiently describes these objects, the claim chart can be reformulated in order to better define the claimed subject matter.

On the other hand, the compound claims containing generic expressions, such as "pharmaceutically acceptable salts", "agriculturally acceptable salts", "immunologically acceptable salts" and “N-oxides” can 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; and 2) the person skilled in the art is aware of routinely employed salts in his/her area of expertise.

2.5 Prodrugs

The chemical compounds can 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 compounds than the drug) which, after administration, undergo biotransformation, leading to pharmacologically active compounds.

Prodrugs are usually developed from the obtainment of derivatives of certain functional groups of a particular compound, with the purpose of optimizing the physical-chemical, biopharmaceutical or pharmacokinetic properties of the pharmacologically active compounds, overcoming several barriers regarding drug formulation and release, 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 matter follows the same guidelines applied to chemicals in general. Especially with regard to the analysis of the non-obviousness requirement, it is important to note that in certain cases, a strategy known to improve the pharmacological or pharmacotechnical properties of drugs and can lead to an effect that would not result in an evident manner to a person skilled in the art.

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

2.6 Reaction intermediate 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 their identity. For simplicity purposes, reference to a "chemical compound" will include "group of chemical compounds." Within these Guidelines, intermediates may be intermediate compounds per se or starting materials (precursors).

Of course, there may be chemical compounds which, besides functioning as precursors (intermediates) of a particular chemical compound, also have end uses, such as pesticides, drugs, coloring agents, etc. However, in this case, that is, when they are in their function as drugs, etc., they will no longer be "intermediaries" in the sense of these Guidelines and should be assessed 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 the so-called "ancillary invention", in which the main invention may be a final chemical compound or a process of obtaining a chemical compound.

When the intermediate compound is not the main invention it should be assessed 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 its process of obtaining. The Guidelines for Examination of Patent Applications Block I – paragraphs 3.119 to 3.125 are applicable.

Note that, in both cases, the claims relating to intermediate(s) are necessarily product claims and should be treated as such by applying the most appropriate directions established in these Guidelines. Also in both cases claims targeted at the process of obtaining the intermediate(s) are accepted.

2.6.1 Intermediate compounds as main invention

Claims relating to the intermediate compounds(s) are necessarily chemical compound claims and the technical analysis of said subject matter follows the same guidelines applicable to chemicals in general.

The inventiveness of an intermediate must be assessed in view of its application as an intermediate, and its differences in relate to the prior art compounds. Thus, if the closest prior art discloses compounds similar to the claimed intermediate, but does not suggest its application in the production of other compounds, i.e., their application as intermediates, it is understood that it would not be obvious or evident to a person skilled in the art to use compounds similar to those in the art as synthesis intermediates.

In the case wherein the closest prior-art compounds have the function of an intermediate, the differences between the claimed (intermediate) compound and those of the prior art must be observed, in order to evaluate whether these differences are actually obvious, considering the function of the claimed compound as an intermediate.

2.6.2 Intermediate compounds as 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/activity/purposes of the main invention and the intermediate are different.

Where the intermediate compound is not the main invention, it should be assessed 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 its process of obtaining. The Guidelines for Examination of Patent Applications Block I – paragraphs 3.119 to 3.125 are applicable.

2.6.3. Process for obtaining intermediate compounds

A process for obtaining an intermediate may be the main invention of the patent application, but the most common is that it is an accessory invention for the main invention of a final compound or even an intermediate.

In the first case, in which the process of obtaining the intermediate is the invention, the claims directed to the process of obtaining the intermediate should define:

(1) the starting material, the product obtained and the means to transform the former into the latter and;

(2) the several steps needed to arrive at the proposed object.

2.7 Chemical compounds found in nature

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

Chemical compounds synthetically obtained which have naturally occurring correspondents and which cannot be distinguished from those found in nature are also not considered to be invention. This aspect was addressed in more detail in the Guidelines for Examination of Patent Applications, Block II, paragraph 1.43, and in the Guidelines for Examination of Patent Applications in the Biotechnology Area, item 4.2.1.1.

2.8 Patent applications directed to the selection of chemical compounds

Some patent applications can relate to a selection of compounds of a broad class of compounds described in

the art, such as, for example, compounds defined by generic formulas of the Markush type. Usually, the prior document refers to a novel class of chemical compounds.

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

In general, to be considered novel, the selected chemical compound may not be specifically disclosed in the prior art in the form of examples, tests, results, lists, tables, nomenclature, individualized structural formula or method of preparation. With regard to non-obviousness, the selection of said compound cannot result in an obvious or evident manner from the prior art for a person skilled in the art. Invariably, as it is a selection of compounds already described generically in a prior document, the assessment of the non-obviousness requirement of the patent application directed to the selection of compounds involves the presentation of comparative data regarding the state of the art. As defined in Block II of the Guidelines for Examination of Patent Applications, paragraphs 4.19 and 5.32, the comparison must be made with respect to the closest state of the art, which, in this case, corresponds to the compound(s) having greater structural similarity specifically disclosed in the art.

Hereinafter, there are some examples that illustrate the three situations which may occur in the technical examination of patent applications directed to the selection of chemical compounds: 1) selected compounds lacking novelty and inventiveness; 2) selected compounds deemed novel, but devoid of inventiveness and; 3) novel and inventive selected compounds.

Example 1: Compounds lacking novelty and inventiveness

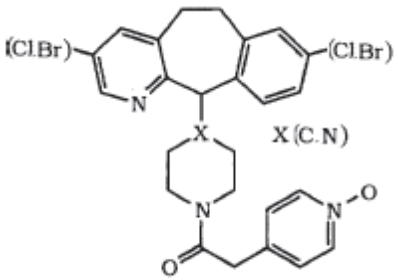
Invention

Tricyclic amide compounds useful in the treatment of proliferative diseases.

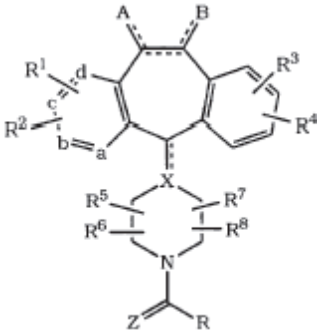
Prior Art

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

Invention



Prior Art



Technical examination

The selected chemicals represent a small group among the compounds generically disclosed in the Markush formula of the prior art document. Said selected compounds in the application under examination do not correspond to the compounds exemplified in the prior art document. however, said compounds were foreseen among the said preferred compounds in the prior art document. Therefore, the claimed compounds are considered to have been specifically disclosed in the state of the art (Guidelines for Examination of Patent Applications, Block II, paragraphs 4.21 to 4.23) and do not fulfill the novelty requirement.

In order to demonstrate the inventiveness, the Applicant filed a series of biological tests comparing the selected compounds with compounds having greater structural similarity specifically disclosed in the prior art.

However, considering that the claimed compounds are not novel, they also are obvious.

Example 2: Novel compounds, lacking inventiveness

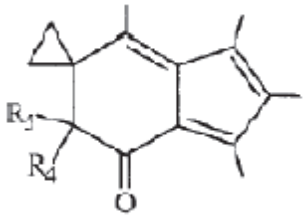
Invention

The patent application relates to analogous compounds of illudins having anti-proliferative activity for the treatment of tumors in mammals.

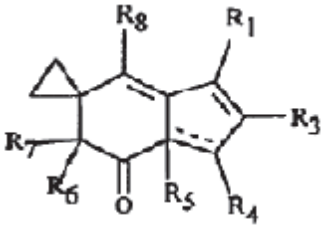
Prior art

The prior art describes generically, in the Markush formula, illudin analogous substances useful as anti-proliferative agents.

Invention



Prior Art



Technical examination

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

The Applicant has submitted the results of tests comparing the anti-proliferative activity among the claimed compounds and the compounds having greater structural similarity specifically disclosed in the prior art. The results did not show an unobvious effect compared to the prior art, since the anti-proliferative activity of the claimed compounds was very similar to that of the compounds disclosed in the prior art (Guidelines for Examination of Patent Applications, Block II, paragraph 5.33). Therefore, although the claimed compounds are considered to be novel, they do not meet the non-obviousness requirement.

Example 3: Novel and inventive compounds

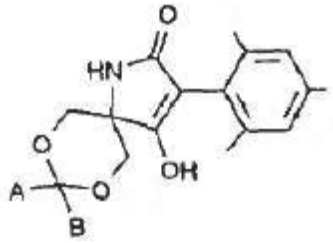
Invention

The patent application refers to cyclic ketoenols substituted with phenyl, processes for their preparation and their use in pesticide and herbicidal compositions.

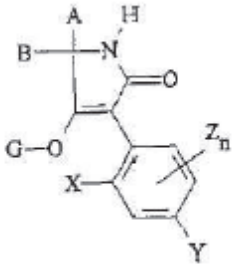
Prior Art

The prior art presents a generic description of cyclic ketoenols having pesticide and herbicidal activity, which include the compounds selected in the patent application under consideration.

Invention



Prior Art



Technical Examination

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

As proof of the inventiveness of the claimed matter, test data was provided which clearly demonstrate the non-obvious technical effect of the claimed compounds compared to compounds of greater structural similarity that are specifically disclosed in the prior art. Thus, the selected compounds were considered non-obvious to a person skilled in the art (Guidelines for Examination Patent Applications, Block II, paragraph 5.34).

3 Stereoisomers

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

The enantiomers are molecules which have chiral center and are non-superimposable mirror images of each other. Diasteroisomer compounds are stereoisomers that are not mirror images of each other and have different physical-chemical properties.

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

A stereoisomeric mixture is a mixture of stereoisomers in any proportion.

A racemic mixture is a stereoisomers mixture equimolar.

3.1 Enablement

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

Analytical techniques such as circular dichroism, nuclear magnetic resonance (with addition of the chiral shift reagent or not), circular birefringence, optical rotary dispersion chromatography (with chiral column), polarimetry and single crystal X-ray diffraction can be used for the characterization of the claimed enantiomer/atropisomer/diastereomer.

The parameters of the process of obtaining the stereoisomer, either by asymmetric synthesis or by purification process subsequent to the synthesis of the compound should be specified in the specification, to ensure reproducibility by a person skilled in the art. Due to the possibility of racemisation of the chiral compounds during their process of obtaining, it is important that the specification discloses the reagents used (specially in the step of formation of the chiral center), the reaction conditions, the methods of isolating and purifying the

stereoisomer obtained by said process. The specification should also describe the possible enantiomeric excess obtained and the method of analysis used for its measurement.

3.2 Clarity

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

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 claim chart can be reformulated in order to better define the claimed subject matter.

3.3 Novelty

The stereoisomer compounds are deemed novel if the prior art does not describe the claimed enantiomer/atropisomer/diastereomer. Novelty will also be acknowledged when enantiomer/atropisomer/diastereomer isolated from nature have been described in the prior art and the presently claimed matter is directed to an antipode thereof.

However, since the prior art has already disclosed the compound in a stereoisomeric mixture, such as a racemic mixture, the pure enantiomer or atropisomer compounds, themselves, are not considered novel, since the stereoisomeric mixture already contains both stereoisomers. It is emphasized that, when the prior art does not specify the absolute configuration of the chiral centers of the compounds described, nor any chiral influence in the synthesis process of such compounds is observed, it is assumed that the distribution of the enantiomers occurs equally, i.e., it is a racemic mixture.

In the case of patent applications that relate to diasteroisomers, the novelty is confirmed when the prior art does not specifically describe the claimed diastereomer. In some cases, the assessment of novelty of the claimed diastereomer becomes possible only through presentation of characterization data of the known compound so as to draw a comparison between the claimed diastereomer and the state of the art. In this case, the same analytical techniques employed for characterizing the claimed diastereomer must be applied to the stereoisomer samples disclosed in the art.

The composition containing only one of the stereoisomers is considered novel even if the state of the 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 also protecting the racemic composition or other composition containing stereoisomers already described in the art. Particularly, the use of the term **consist**, viewed as a restrictive term, limits the constituents of a composition only to those defined in the claim (Guidelines for Examination of Patent Applications, Block I, paragraph 3.48). For example, a claim directed to a "*Composition characterized by **consisting** of the R enantiomer of compound X and vehicles*" excludes the presence of any other stereoisomer different than the one defined in the claimed composition. It should be noted that the term “vehicles” (excipients, adjuvants, carriers, etc.) is related to the substances that carrier 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 **comprise** broadens the scope of protection of the composition claims, compromising the novelty. For example, the wording of a claim directed to a "*Composition characterized by **comprising** the R enantiomer of compound X and vehicles*" does not limit the constituents only to the elements defined in the claimed composition, and may comprise, besides the R stereoisomer, other constituents including the S stereoisomer (Guidelines for Examination of Patent Applications, Block I, paragraph 3.49).

However, a wording directed to a “*Composition characterized by **comprising** the R enantiomer of compound X and vehicles, wherein said composition is free of S enantiomer of compound X*” could be considered novel, since it excludes the presence of the S enantiomer of the claimed composition.

A composition consisting of a stereoisomeric mixture of defined constitution (given stereoisomeric excess) will be considered novel since it has not been previously disclosed in the art. For example, a claim directed to a "*Composition characterized by* ***comprising*** *the R enantiomer of compound X and vehicles, wherein the enantiomeric excess is greater than 70%*" 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 that purpose. The same is applicable for applications that relate to diastereoisomers of a compound, when the prior art anticipates the claimed use for said compound.

If the application relates to a new use of an isolated stereoisomer compound, the examination must be based on the Guidelines for Examination of Patent Applications, Block I, paragraphs 3.73 to 3.76 and Block II, paragraph 4.18 and in the Guidelines for Examination of Patent Applications – Chemistry, item on New Uses of Known Products.

3.4 Non-obviousness

When the prior art compound purpose is known, there is an expectation that the pure stereoisomer of this compound presents this same property. Thus, it is considered that a person skilled in the art would be motivated to obtain this stereoisomer with the purpose of identifying the most appropriate form for industrial use, for example, the more active stereoisomeric form. The same position should be assumed for the assessment of the non-obviousness requirement of compositions containing stereoisomers.

If the application relates to a new use of an isolated stereoisomer compound, the examination must be based on the Guidelines for Examination of Patent Applications, Block I, paragraphs 3.73 to 3.76, and Block II, paragraphs 5.40 to 5.45 and the Guidelines for Examination of Patent Applications – Chemistry, item on New Uses of Known Products.

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 the molecules in an ordered crystal lattice. Amorphous solids consist of solids with disordered arrangements of molecules and do not have a defined crystal lattice.

4.1 Enablement

To characterize the crystalline form, the specification shall contain in the filing date, the identification data obtained from solid physicochemical characterization techniques, such as those exemplified below or by validated alternative techniques that best identifies:

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

b. X-Ray Powder Diffraction (Powder XRD);

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

d. Spectrometry in the Infrared Region;

e. Raman Spectroscopy;

f. Electronic Microscopy;

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

It should be noted that the single-crystal XRD technique is sufficient for the perfect characterization of the crystalline structure of the solid. Not being provided the single-crystal XRD data, it should be used the powder DRX technique with indexing associated with other methods of physical-chemical identification of solids, so

that the set of techniques is sufficient for unambiguous identification of the crystalline form. It is important to note that techniques more advanced of solid characterization are not provided in these Guidelines and will be assessed regarding the relevance for the identification of the claimed crystalline solid. In the absence of characterization data of the crystalline solid it will be considered that the specification does not describe clearly and sufficiently the object. It should be noted that the presentation of characterization data of the claimed solid after the patent application filing will not be allowed, since it will be considered addition of the subject matter.

The parameters of the process for obtaining the crystalline form must be defined in the specification, in order to ensure reproducibility by a person skilled in the art. Essential parameters in these processes, for example, are indication of solvent(s) and concentration(s) thereof, solvent addition rates, heating and cooling rates, description of the process for obtaining possible 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, namely, that is, to consider that the process is sufficiently described to allow its reproduction by a person skilled in the art, the polymorph obtained by such process must be properly characterized in the specification.

4.2 Clarity and precision of the claims

The identification of a crystalline form is made by physical-chemical parameters that define their structure. The simple designation by names such as, for example, alpha or beta form, form I or II, does not define clearly and precisely the crystalline form. The following are examples of crystalline forms claims with a clear and precise wording.

Example 1:

A crystalline form of compound X characterized by having a melting point of 151°C as measured by differential scanning calorimetry (DSC 2K min-1);

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 relative intensities of 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 X-ray diffractogram;

having maximum peaks at 3338, 1708 and 1431 cm-1 in its infrared spectrum, having maximum peaks at 107.9, 118.2 and 135.0 ppm in its solid-state 13C NMR spectrum and provide maximum peaks at 3080, 1580 and 122 cm-1 in its Raman spectrum.

Example 2:

A crystalline form of compound X characterized by 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 the respective relative intensities of 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

The distinguishing features of the crystalline forms are based on physical-chemical parameters. In general, the closest state of the art is that which discloses the process of obtaining the compound which mostly is not characterized as to 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 art should be presented at the moment of the patent application filing or in the course of the technical examination.

If the state of the art already discloses the claimed crystalline form, even if in admixture with other forms, regardless of its concentration, the crystalline form is not considered to be novel.

If the prior art describes the compound in a non-solid state (e.g., liquid, pasty, or oily), data from physical-chemical characterization of the prior-art compound are dispensable, since under these circumstances there is no doubt about the novelty of the claimed polymorph.

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, as in the shelf life or also in terms of chemical effects.

However, it is important to note that obtaining crystalline solids from a compound is common practice in the industry to enhance the physical-chemical features of compounds in general. Thus, the mere description and 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

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

When a solvate loses solvent molecules incorporated in the crystal lattice (purposely or not) and the crystal retains the structure of the solvate, the solid obtained is called desolvate. This matter should be evaluated as discussed in the section on Polymorph herein, since it refers to a crystalline form consisting of only one type of molecule.

In turn, clathrates are inclusion compounds wherein one molecule (guest) is imprisoned in a cavity of the host molecule or host molecules lattice (e.g., cyclodextrin inclusion complex).

In general, solvates, clathrates and co-crystals have the following characteristics in common:

1) they are all formed of at least two molecules;

2) they all may assume different crystalline forms;

3) they all may have different characteristics according to the structure and crystal constituents.

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

1) a clear and sufficient description of a solvate, clathrate, crystalline complex or co-crystal requires the chemical identity of the molecule and the stoichiometry, which can be determined by thermogravimetric analysis (TGA) techniques, Karl Fischer or other validated techniques that provide such information;

2) if the invention to be protected is a solvate, for evaluation of the claimed matter, the item on Chemical Compound included herein and in the Guidelines for the Examination of Patent Applications issued by the BRPTO must be consulted, since the solvate is considered a chemical compound that is different from its corresponding compound without solvation or anhydrous;

3) if the invention to be protected is a crystalline form (clathrate, co-crystal or solvate crystalline form), it must be characterized physical-chemically using the techniques described in the item on Polymorph herein, in addition to the Guidelines for Examination of Patent Applications issued the BRPTO, in order to define both the constituents and the structure of the crystalline form.

4) the use of generic terms "solvates thereof", "hydrates thereof", "clathrates thereof" and/or "co-

crystals thereof" in claims relating to a compound per se, does not identify the solvates, hydrates, clathrates and co-crystals derivatives of the compound in a clear and precise manner. If the specification of the patent application sufficiently describes these objects, the claim chart can be reformulated in order to better define the claimed subject matter.

6. Compositions, formulations and physical forms of compositions

Claims directed to compositions, formulations and physical forms of compositions are examined according to the Guidelines for Examination Patent Applications, Block II, in paragraphs 7.1 to 7.15.

6.1. Clarity and precision of the claims

As discussed in the Guidelines for Examination of Patent Applications, Block II, paragraphs 7.1 to 7.15, a composition is usually defined only by its constituents. However, the compositions may also be defined by mixed characteristics, so as to include physical form or application characteristics, provided that they are defined quali- and/or quantitatively by their constituents. The following are additional examples of compositions, with an emphasis on the analysis of the clarity and precision of the claims (under Article 25 of the Brazilian Patent Statute).

Example 1:

Claim 1: A pharmaceutical composition, characterized by comprising Compound A and excipients B and C.

Claim 2: The pharmaceutical composition according to claim 1, characterized by being for oral administration

It meets the requirements of Article 25 of the Brazilian Patent Statute, since the composition is defined by its constituents in claim 1 and 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.).

Claim 3: The pharmaceutical composition according to claim 1, characterized by being in the form of capsule.

It meets the requirements of Article 25 of the Brazilian Patent Statute, because the composition is defined by its constituents in claim 1 and the expression "being in the form of capsule" is a further feature of the claimed subject matter.

Claim 4: The pharmaceutical composition according to claim 1, characterized by being for the treatment of asthma.

It meets the requirements of Article 25 of the Brazilian Patent Statute, because 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 in the treatment of asthma.

Claim 5: The pharmaceutical composition according to claim 1, characterized by releasing eighty per cent (80%) of component A in less than 30 minutes.

It meets the requirements of Article 25 of the Brazilian Patent Statute, because the composition is defined by its constituents in claim 1, and the release the component A is an additional feature that informs about the properties of the claimed subject matter.

Example 2:

Claim 1: A pharmaceutical composition, characterized by comprising compound A and excipients B and C for oral administration.

It meets the requirements of Article 25 of the Brazilian Patent Statute, because the composition is defined by its constituents. 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 3:

Claim 1: A pharmaceutical composition for oral administration, characterized by comprising compound A and excipients B and C.

It meets the requirements of Article 25 of the Brazilian Patent Statute, because 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: A pharmaceutical composition characterized by comprising compound A and excipients B and C for treating asthma.

It meets the requirements of Article 25 of the Brazilian Patent Statute, because the composition is defined by its constituents. The information on the use of the composition represents only a further characterization of the composition, restricting the claimed subject matter to the field of products useful in the treatment of asthma.

Example 5:

Claim 1: A pharmaceutical composition comprising compound A and excipients B and C, characterized by being for the treatment of disease Y.

It is not acceptable for lack of clarity (under Article 25 of the Brazilian Patent Statute), because the composition is not characterized by its constituents but rather by its use. In this case, to meet the provisions of Article 25 of the Brazilian Patent Statute, it is possible to reformulate the wording of the claim displacing the constituents of the composition to the characterizing part. (Guidelines for Examination of Patent Applications, Block I, paragraphs 3.04 to 3.09).

If the composition is known in the art, the claim would not be novel, since the characteristic relating to the use of the composition does not confer novelty to the product.

Example 6:

Claim 1: A composition characterized by releasing eighty percent (80%) of active ingredient in less than 30 minutes.

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

Example 7:

Claim 1: An insecticidal composition characterized by being in the form of spray.

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

Example 8:

Claim 1: A pharmaceutical composition characterized by comprising compound A and its excipients B and C to be used in the form of extended release tablets capable of releasing eighty percent (80%) of component A in

less than 30 minutes.

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

Example 9:

Claim 1: A tablet characterized by comprising compound A and excipients B and C.

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

Example 10:

Claim 1: A pharmaceutical form characterized by being in the form of a tablet comprising 100 mg of A, 220 mg of B and 200 mg of C.

It fulfils the requirements of 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: A pharmaceutical composition characterized by comprising compound A and excipients B and C.

Claim 2: The pharmaceutical composition according to claim 1, characterized in that the dosage of A varies from 45 to 90 mg by kg of the patient.

It is not acceptable for lack of clarity (under Article 25 of the Brazilian Patent Statute), since the additional feature of dependent claim relates to the administration method of the pharmaceutical composition, which is part of a therapeutic regimen and is not related to the product. The added feature does not add information about the product per se, which creates an inconsistency to the claimed subject matter.

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

It is not acceptable for lack of clarity (under Article 25 of the Brazilian Patent Statute), since the additional feature of dependent claim relates to the administration method of the pharmaceutical composition, which is part of a therapeutic regimen and not a product. The added feature does not add information about the product per se, which creates an inconsistency to the claimed subject matter.

Example 12:

Claim 1: A composition characterized by comprising a compound A and a compound B.

Claim 2: The composition according to claim 1, characterized by optionally comprising other active ingredients.

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

If the specification of the application contains a sufficient description of so-called "active ingredients", the claim chart may be reformulated in order to restrict the active ingredients to those described in the specification.

Example 13:

Claim 1: A gray soda-lime glass composition characterized by comprising an element A and an element B at

concentrations x and y, respectively, present as coloring agents, wherein the glass has an overall light transmission < 20% for a glass thickness of 4 mm.

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

It fulfils the requirements of Article 25 of the Brazilian Patent Statute, as the composition is characterized by its constituents and their concentrations. The light transmission (physical parameter) is an additional feature of the claimed matter.

Example 14:

Claim 1: A fertilizer composition characterized by comprising the raw material A (e.g. ammonium nitrate) and a raw material B (e.g. calcium sulfate) at concentrations X and Y, respectively.

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

It fulfils the requirements of Article 25 of the Brazilian Patent Statute, as the composition is characterized by its raw materials and their concentrations. The nutrients and their concentrations are additional characteristics of the composition.

Example 15:

Claim 1: A fertilizer composition characterized in that it consists of elements X, Y and Z (e.g. carbon, hydrogen, nitrogen, phosphorus, potassium, etc.).

It is not acceptable for lack of clarity (under Article 25 of the Brazilian Patent Statute), because the composition is not characterized by raw materials containing these elements and it does not specify their concentrations.

7 Combinations of chemical compounds

A combination is the association of two or more compounds targeting a particular final product. The combination may be contained in a single form or in separate forms for simultaneous application. The examination of combinations should take into account paragraphs 5.24 to 5.30 and 7.16 to 7.23 of the Guidelines for Examination of Patent Applications, Block II.

In the particular case of the inventions related to combinations, the interaction between the associated compounds should produce an unexpected effect, such as, for instance, a synergistic or additive effect, which does not correspond to an additive effect, that is, the mere sum of individual effects of each compound composing said combination.

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

Proof of the unexpected effect obtained from a combination frequently involves presentation of data that enables a comparison between the effects observed for the respective compounds when used separately and those obtained from a combination of these compounds under the same experimental conditions.

It should be noted that the alleged non-obvious effect cannot be suggested in the prior art, such as, for example, in combinations of compounds of the same class than the compounds of the combination in question (Guidelines for Examination of Patent Applications, Block II, paragraph 7.19).

7.1 Enablement, clarity and precision of the 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 “Markush” formula, such as, for example, "A combination characterized by comprising a compound as defined by general formula (I) in association with compound A", special attention should be given to the clarity and precision of the wording of the claim and the Guidelines for Examination of Patent Applications, Block II (paragraphs 6.13 and 6.14) should be followed.

7.1.2 Combinations comprising one or more classes of chemical compounds

The invention relates to a combination comprising one or more compound groups defined by their chemical class or their mechanism of action, for example, "A pesticidal combination characterized by comprising a pyrethroid compound and a enzyme inhibitor compound X".

The definition of the compounds of the combination by their chemical class or mechanism of action in a generic way, without specifying which one(s) is(are) the exact compound(s) included in the combination is not sufficient to clearly define the matter to be protected, which is at variance with the provisions of Article 25 of the Brazilian Patent Statute.

If the specification contains a sufficient description of the compounds which are classified in the classes of compounds according to the invention, the claim chart may be reformulated to restrict the compounds which have been described in the specification.

7.1.3 Combinations comprising, optionally, other active ingredients

Applications relating to a new combination may include, besides the main claim related to the combination, ancillary claims such as:

"A combination characterized by comprising compounds A and B, and optionally other active ingredients."

In such situations, special attention should be given to the clarity and precision of the wording of the combination claim, because the mere mention of the term "and optionally other active ingredients" is not enough to clearly define the claimed subject matter, which is contrary to the provisions of Article 25 of the Brazilian Patent Statute.

If the specification of the application contains a sufficient description of compounds that are classified as other active ingredients according to the invention, the claim chart may be reformulated in order to better define the matter to be protected.

7.1.4 Combination wherein the compounds are in separate forms

In applications related to combinations wherein the compounds are in separate forms, the specification must provide evidence that such combinations are obtainable in the form of a product for simultaneous application, although it is claimed by a kit (Guidelines for Examination of Patent Applications, Block II, paragraph 7.11).

<u>Example:</u>

Specification:

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

but simultaneously.

Claim chart:

Claim 1: "A synergistic herbicidal combination characterized by comprising compound A and compound B."

Claim 2: "A method for controlling weeds, characterized in that the plants are treated with the combination as defined in claim 1."

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

Technical examination:

Claims 1 and 2 may be acceptable provided they meet the patentability requirements. On the contrary, claim 3 cannot be accepted, since it includes the possibility of applying the compounds A and B sequentially. Bearing in mind that a combination refers to a product of association of two or more compounds for simultaneous application, the possibility of a sequential application would be inconsistent with the matter to be protected.

8 Analogous processes

Analogous processes comprise starting materials and/or final products which exhibit novelty and non-obviousness over the prior art, although such processes involve the combination or use of procedures known in the art.

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

Thus, the claims directed to analogous processes can be generally interpreted as accessory claims, because, by definition, novelty and non-obviousness are a function of the presence of these requirements in the product and/or starting material. In addition to analogous processes relating to synthesis of chemical compounds which exhibit novelty and non-obviousness, the concept can also be extrapolated for those processes relating to the production of pharmaceutical compositions, agrochemical compositions, medicaments, catalysts, lubricants, pesticides or herbicides, among others.

If the technical examination considers that the starting materials and/or final products do not exhibit novelty and/or non-obviousness, the claimed analogous processes will not be accepted for lack of novelty and/or non-obviousness over the state of the art.

In another situation, if the technical examination considers that the starting materials and/or final products do not exhibit novelty and/or non-obviousness, but that the claimed processes involve novelty and/or non-obviousness, such process claims must be examined as common process claims, that is, it will no longer relate to an analogous process claim.

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

9 New uses of known products

This section relates to peculiarities of the technical examination of inventions related to new uses of known products, especially new medical uses, complementing the Guidelines for Examination of Patent Applications, Block I, paragraphs 3.73 to 3.76 and Block II, paragraphs 4.18 and 5.40 to 5.45.

Protection of a new use claim is given to the set of use of the known substance for a new purpose. Thus, the specification shall describe clearly and sufficiently the claimed new use.

When the application seeks protection for a new use of various compounds, e.g., identified in a "Markush

formula," only the use of compounds which has been effectively been demonstrated in the specification in order to verify the claimed use will be considered to have been sufficiently described. Although theoretically the compounds defined by a certain “Markush formula” can have similar activity, it is not possible to extrapolate the new use of a single compound to all the others, unless tests are provided proofing this equivalence in the effect.

The application which is related to a new use of a group of compounds will be deemed to have unity of invention if said compounds are structurally related (Markush formula, for example) or have the same mechanism of action. In the pharmaceutical field, the application that relates to a new medical use for a range of diseases that have the same etiology will also be considered to involve unity of invention.

9.1 New medical use

9.1.1 Novelty

To be considered novel, the new medical use invention should disclose the application 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 art.

Features related to the use of compound, such as therapeutic regimen (dosage, route of administration/application, dose range) and/or the 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 for manufacturing a medicament for treating disease Y" and the application claims the "use of compound X for manufacturing 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 a 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 in etiology of disease related to the use disclosed in the art.

3. The new use cannot be inferred from the drug structure-activity relationship compared to structurally related molecules, namely, from the structural analogy with other compounds having the same activity as claimed, already disclosed in the art.

4. The new use cannot be inferred from the disclosure of adverse effects known to the art for the drug in question.

5. The new use cannot be inferred from the use of the compound for treating a symptom of a disease already disclosed in the prior art, although the claimed use concerns a different disease.

9.1.3 Enablement

It should be noted that the protection of a new medical use claim is given to the set of use of the known substance for manufacturing a medicament for a new therapeutic use. Thus, the specification shall describe clearly and sufficiently the new claimed use.

The specification should present evidences that proof the new claimed use at the filing moment. In the absence of a proof of this use, it is considered that the essential technical feature of claim is not supported in the specification and thus the subject matter is not sufficiently described. Results of in vitro tests can indicate

a new therapeutic use; however, often they are not confirmed in vivo, due to pharmacokinetic aspects, among others related to the behavior of the drug within the organism. Therefore, it is not always possible to extrapolate the results of the in vitro assays to a real therapeutic use, unless complementary information proofing this effect equivalence are presented. Regarding tests performed in animals, the adopted models must present the possibility of extrapolation to human beings or animals to be treated.

If the application seeks protection for a second medical use of compounds defined by a "Markush formula", the use of the compounds will only be considered sufficiently described when they are effectively demonstrated. Although theoretically the compounds defined by a certain "Markush formula" can have similar activity, it is not possible to extrapolate the use of a single compound to all the others, unless tests are provided proofing this equivalence of effect.

According to paragraph 3.89 of Block I of Guidelines for Examination of Patent Applications, the Applicant has the responsibility of proofing the support of claims and additional proofs are acceptable in the course of the technical examination, provided that they are addressed exclusively to complement the information already disclosed in the application as initially filed.

9.1.4 Clarity and precision of the claims

New use claims for preparing a medicament must specify the disease to be 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 they cause indefiniteness as to the matter to be protected.

Claims directed to a new medical use which refer to the condition treated in terms of their mechanism of action, for example, "use of compound X for preparing a medicament for treating a disease by selective placement of a serotonin receptor" or "use of the compound X for preparing a medicament that inhibits serotonin reuptake" are not acceptable, since they do not define the disease in question clearly and precisely.

Extracts contained in the new medical use claims related to the therapeutic regimen and patient group do not define the use of a compound for preparing a medicament and thus are not accepted by causing indefiniteness to the claimed matter. Complementary examples related to new medical use are presented below.

Example 1:

Claim: "Use of the product (or compound or active principle) X, characterized by being for preparing a medicament for treating disease Y."

It fulfils the requirements of Article 25 of the Brazilian Patent Statute, because the use of the product is characterized, in a clear and precise manner, for preparing a medicament for treating a defined disease.

Example 2:

Claim: "A product X characterized by being used as a medicament."

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

Moreover, since the product is known in the art, it would not exhibit novelty (Guidelines for Examination of Patent Applications, Block I, paragraph 3.74).

Example 3:

Claim: "Product X characterized by being used for the treatment of disease Y."

It is not acceptable for lack of clarity (under Article 25 of the Brazilian Patent Statute), since the product is being

defined by its use and not by its technical characteristics.

Moreover, since the product is known in the art, it does not exhibit novelty (Guidelines for Examination of Patent Applications, Block I, paragraph 3.74).

Example 4:

Claim: "Use of product X, characterized by being for treating disease Y."

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

Example 5:

Claim: "Process for treating disease Y, characterized by administering product X."

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

Example 6:

Claim: "Use of compound X for preparing a medicament for inhibiting receptor Y."

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

Example 7:

Claim: "Use of compound X for preparing a medicament for treating CNS disorders or syndromes."

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

Example 8:

Claim: "Use of the product X, characterized by being for preparing a medicament for treating disease Y, which consists of orally administering the medicament three times per day."

It is not acceptable for lack of clarity (under Article 25 of the Brazilian Patent Statute), since the additional feature of claim ("...consists of orally administering the medicament three times per day") is inconsistent with the claimed subject matter, since it refers to the administration method (part of a therapeutic regimen), rather than the use (process for preparing a medicament for treating disease Y).

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