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Note C. 8828

Additional inputs for the preparation of documents to the 30th Session of the Standing Committee on the Law of Patents¹

Brazil

February 15, 2019

Further study on inventive step (part 3)

Topics suggested in paragraph 8 of Annex to document SCP/24/3

Assessment of inventive step in chemical sector

The analysis of the inventive step requirement is regulated in INPI Guidelines for Examination of Patent Applications, Block II, Paragraphs 5.1 to 5.61 (INPI Resolution No. 169, of July 15, 2016).

DEFINITION

The invention is considered to involve an inventive step if, in view of the prior art, it is not obvious or evident to one skilled in the art.

The term "obvious" (or "evident") means that the subject matter does not go beyond the normal development of technology, but only derives in a clear or logical way from the state of the

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



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art, i.e. something that does not involve the exercise of any skill or capability beyond of what is expected of a technician in the subject.

If the person skilled in the art can arrive at the invention solely by logical analysis, inference or without undue experimentation based on the state of the art, the invention is considered obvious and, therefore, has no inventive step.

PERSON SKILLED IN THE ART

The “person skilled in the art” is presumed to be possessed of average knowledge, with a technical-scientific level, and/or one with a practical operational knowledge of the subject matter, who is aware of what was common general knowledge in the art at the time of the application filing. He is presumed to have had at his disposal the means and capacity for routine work and experimentation which are normal for the field of technology in question. There may be instances where it is more appropriate to think in terms of a group of persons, e.g. a research or production team. This may apply, particularly, to certain advanced technologies such as computers and nanotechnology. The definition of the person skilled in the art used for purposes of inventive step evaluation is the same used for sufficient disclosure analysis.

INVENTIVE STEP EVALUATION

In inventive step evaluation, not only the technical solution must be taken into consideration, but also the technical field of the claimed invention, the problem to be solved and the technical effects that the invention provides over the closest prior art.

Three steps are employed to determine if an invention is obvious when compared to the prior art:

1. Determination of the "closest prior art";
2. Determination of the distinguishing characteristics of the invention and/or the technical problem actually solved by the invention, and



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3. Determination whether, in view of the technical problem considered, and starting from the closest state of the art, the invention is or is not obvious to a person skilled in the art.

INVENTIVE STEP IN CHEMICAL INVENTIONS

The analysis of the inventive step requirement is regulated in INPI Guidelines for Examination of Patent Applications, Block II, Paragraphs 5.1 to 5.61 (INPI Resolution No. 169, of July 15, 2016), and the INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208, of December 27, 2017).

COMPOUNDS DEFINED BY MARKUSH FORMULA

The analysis of the inventive step requirement of inventions related to compounds defined by Markush Formula is regulated in INPI Guidelines for Examination of Patent Applications, Block I, Paragraphs 3.38 and 3.126 to 3.128 (INPI Resolution No. 124, of December 4, 2013), and Block II, Paragraphs 6.1 to 6.14 (INPI Resolution No. 169, of July 15, 2016).

“Markush Formula” is a basic chemical structure representation of a group of compounds, which can be replaced by one or more variable substructures, which are accompanied by a list of definitions of these variable portions.

Therefore, a multiplicity of compounds may be protected in a patent from a unique representation structure (INPI Guidelines for Examination of Patent Applications, Block II, Paragraphs 6.2 and 6.4).

In general, the compounds defined in a new Markush Formula will meet the inventive step requirement if, based on the prior art knowledge, a person skilled in the art would not be motivated to carry out the proposed structural modifications. In cases of structural similarity, the evaluation of the inventive step involves the recognition of the existence of an unexpected technical effect, often evidenced by comparative data in relation to the state of the art (INPI Guidelines for Examination of



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Patent Applications, Block II, Paragraphs 6.7 and 6.8).

SALTS, N-OXIDES, ESTERS AND ETHERS

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

If a particular salt, N-oxide, ester or ether changes the properties of the base compound in a manner not obvious to a person skilled in the art, such a salt, N-oxide, ester or ether will be considered to comply with the inventive step requirement. On the other hand, the mere 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 in relation to the state of the art, does not render such compounds inventive.

PRO-DRUGS

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

It is important to note that in certain cases a known strategy for improving the pharmacological or pharmacotechnical properties of drugs may lead to an effect that would not be apparent to one skilled in the art.

INTERMEDIATES COMPOUNDS

Intermediates, in the strict sense, are chemical compounds (or groups of chemical compounds) that are used in the production route of another chemical compound (or group of



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chemical compounds), through chemical(s) and/or physical changes(s), losing their identity.

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

The inventive step of an intermediate compound should be judged by its application as an intermediary and also by its distinguish characteristics in relation to prior art compounds. Thus, if the closest prior art discloses similar compounds to the claimed intermediate but does not suggest its application in obtaining other compounds, i.e. their application as intermediates, it is understood that it would not be obvious or evident to one skilled in the art to use similar compounds to those of the prior art as reaction intermediates.

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

STEREISOMERS

The analysis of the inventive step requirement of inventions related to stereoisomers is regulated in INPI Guidelines for Examination of Patent Applications – Chemistry, Item 3.4 (INPI Resolution No. 208, of December 27, 2017).

When the application of a given racemic mixture is known in the prior art, there is an expectation that the pure stereoisomer composing this mixture has the same purpose. Thus, it is considered that the person skilled in the art would be motivated to isolate stereoisomers in order to identify the most suitable form for industrial use, such as, for example, the more active stereoisomeric form. The same reasoning should be applied to the inventive step analysis of compositions containing such stereoisomers.

If the application concerns a new use of an isolated stereoisomer compound, the



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examination should be based on the INPI Patent Application Examination Guidelines, Block I, Paragraphs 3.73 to 3.76 (INPI Resolution No. 124, of December 4, 2013), and Block II, Paragraphs 5.40 to 5.45 (INPI Resolution No. 169, of July 15, 2016), and the INPI Guidelines for Examination of Patent Applications - Chemistry, Item 9 (INPI Resolution No. 208, of December 27, 2017).

POLYMORPHS

The analysis of the inventive step requirement of inventions related to polymorphs is regulated in INPI Guidelines for Examination of Patent Applications – Chemistry, Item 4.4 (INPI Resolution No. 208, of December 27, 2017).

Although they share the same chemical structure, and taking into account that the possibility of forming different crystal lattices is a peculiar property of the solid, polymorphic forms may have different physicochemical properties, which influence the shelf life and/or chemical effects.

However, it is important to note that the search for crystalline solids of a compound is a common industry practice for improving the physicochemical characteristics of compounds in general. Thus, the mere description and characterization of an alternative crystalline solid of a known compound, when dissociated from an unobvious property or a technical advance related to the prior art, does not render such polymorphs inventive.

SOLVATES, CLATHRATES, CO-CRYSTALS

The analysis of the inventive step requirement of inventions related to solvates, clathrates, and co-crystals is regulated in INPI Guidelines for Examination of Patent Applications – Chemistry, Item 5 (INPI Resolution No. 208, of December 27, 2017).

In some crystalline solids, the solvent may be incorporated into the compound crystalline network in stoichiometric or non-stoichiometric proportions. These molecular adducts are called solvates, also known as pseudopolymorphs. When the water is the crystallization solvent, the



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resulting solid is called hydrate. Clathrates are inclusion compounds in which a guest molecule is entrapped in a cavity of the host molecule or the host molecule network (e.g., cyclodextrin inclusion complexes). In general, solvates, clathrates, and co-crystals have the following common characteristics:

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

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

- If the claimed invention is a solvate, the instructions contained in the Chemical Compound Item of INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208, of December 27, 2017), and in the INPI Patent Application Examination Guidelines, Block II (INPI Resolution No. 169, of July 15, 2016) must be consulted;
- If the claimed invention is a crystalline form, it must be physicochemically characterized by the techniques described in the Polymorph Item of INPI Guidelines for Examination of Patent Applications – Chemistry (INPI Resolution No. 208, of December 27, 2017), and in the INPI Patent Application Examination Guidelines, Block II (INPI Resolution No. 169, of July 15, 2016).

COMBINATION OF COMPOUNDS

A compound combination is the association of two or more compounds targeting a particular end product. The compound combination may be contained in a single form or in separate forms for simultaneous use. For the examination of this matter, Paragraphs 5.24 to 5.30



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and 7.16 to 7.23 of the INPI Patent Application Examination Guidelines, Block II (INPI Resolution No. 169, of July 15, 2016), should be considered.

In the case of combinations-related inventions, the interaction between the associated compounds should produce an unobvious effect, for example a synergistic or supra-additive effect, which does not correspond to an additive effect, i.e. to the mere sum of the effects of each compound that constitute said combination.

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 does not meet the inventive step requirement, since said combination corresponds to a predictable association of known compounds to generate an expected technical effect.

Evidence of the non-obvious effect of a combination often involves data presentation for a comparison between the observed effects when the respective compounds are used alone and as a combination, under the same experimental conditions.

It should be noted that the alleged non-obvious effect cannot be suggested in the prior art, for example in combinations of compounds belonging to the same class of the compounds under analysis (INPI Patent Application Examination Guidelines, Block II, Paragraph 7.19).

NEW MEDICAL USE

The analysis of the inventive step requirement of inventions related to new use of Known compounds is regulated in INPI Guidelines for Examination of Patent Applications – Chemistry, Item 9.1.2 (INPI Resolution No. 208, of December 27, 2017).

In the case of new medical use inventions, some aspects must be observed to assess the inventive step requirement:

1. The action mechanism of the compound involved in the new use should not be inferred from its action mechanism already revealed in the prior art.



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2. The new use shall be related to the treatment of a disease whose etiology is different from the disease etiology disclosed in the prior art.
3. The new use cannot be inferred from the structure-activity relationship of the drug compared to structurally related molecules, i.e. from the structural analogy with other compounds having the same activity now claimed, already disclosed in the prior art.
4. The new use cannot be inferred from the known adverse effects disclosed in the prior art related to the drug in question.
5. The new use cannot be inferred from a symptom already disclosed in the prior art for another disease, although the claimed use refers to a therapeutic application (different disease).