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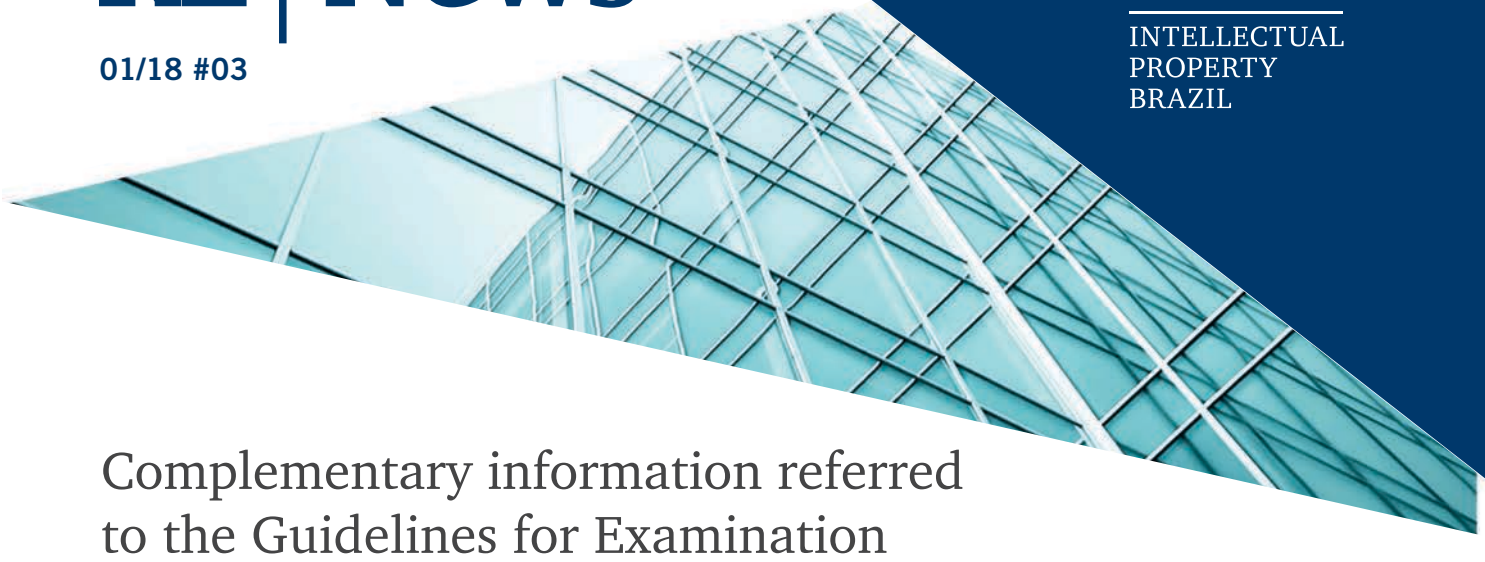

Complementary information referred to the Guidelines for Examination of Patent Applications in the field of Chemistry

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As informed in our Newsletter No. 01/2018, the Brazilian Patent Office (BPTO) recently published Resolution No. 208, which entered into force on January 2, 2018 by means of publication made in the Official Gazette No. 2452.

This Resolution established the first Guidelines specifically related to the particularities in the Examination of inventions in the Chemical Field. The content of the Guidelines is in line with the Guidelines for Examination of Patent Applications - Resolution No. 124/2013 (Part I) and Resolution No. 169/2016 (Part II) - and confirms the aspects proposed by means of the public consultation published in the Official Gazette of March 17, 2017.

Some specific topics have been included in the text of the new Guidelines, particularly when compared to the dispositions of the second part of the Guidelines for Examination of Patent Applications, which refers to patentability aspects (Resolution No. 169/2016), such as:

- Salts, N-oxides, Esters and Ethers;
- Prodrugs;
- Intermediate of reaction;
- Stereoisomers;
- Polymorphs;
- Solvates, Clathrate, Co-Crystals;
- Analogous process.

The new Guidelines address requirements of novelty, inventive activity, clarity and descriptive sufficiency of chemistry-related inventions, and should be understood as a complement to the general Guidelines established in Resolutions No. 124/2013 and 169/2016.

Attention is drawn to the following topics of Resolution No. 208/2017:

Selection Patents

The criteria for examining patentability of selection patent applications have already been detailed in Resolution No. 169/2016, and are fully corroborated by the new Guidelines.

While the general Guidelines (specifically, Resolution No. 169/2016) deal with selection patents of chemical compounds and processes, the new Guidelines only address the selection of chemical compounds.

In general terms, the BPTO's position on selection patents is considered restrictive. To be interpreted as novel, a selected chemical compound must not have been specifically disclosed in the form of examples, tests, results, lists, tables, nomenclature, individualized structural formula or preparation method. The assessment of inventive activity requires the presentation of comparative data of the selected compound in relation to the state of the art.

The main contribution of the new Guidelines in relation to this topic is the presentation of three examples illustrating different situations that may occur during the technical examination of selection patent applications:

1) Selected compounds devoid of novelty and inventive activity;
2) Selected compounds endowed with novelty, but devoid of inventive activity; or
3) Selected compounds endowed with novelty and inventive activity.

Polymorphs

The patentability of crystalline/polymorphic forms has been one of the most controversial issues in the chemical field, and a major point of discussion between the BPTO and ANVISA for several years.

Up to now, although not having defined rules related to the examination of polymorphs, the BPTO has been favorable to the patentability thereof. Nevertheless, the Examiners have been adopting excessively strict positions when it comes to the fulfillment of requirements of novelty, inventive activity and sufficiency of disclosure.

The newly published Guidelines corroborates such a restrictive opinion, mainly regarding the sufficient disclosure of crystalline/polymorphic forms. The BPTO establishes as an absolute requirement that the specification as filed (post-filing data is not allowed) should contain identification data obtained by techniques for physicochemical characterization of solids. When data of single crystal XRD technique is not provided, powder XRD technique with indexation should be used, in association with other methods for physicochemical identification of the solids.

More advanced techniques of characterization of solids not foreseen in the Guidelines will be evaluated by the Examiner as to the pertinence for the identification of the claimed crystalline solid. In the absence of such type of data, it will be considered that the specification does not clearly and sufficiently describe the object.

Novel Uses of Known Compounds

As to the new medical uses, particularly with regard to the descriptive sufficiency of the specification and grounding of the claims, the Guidelines are quite restrictive.

In the case of an objection grounded on alleged insufficiency of disclosure of a new claimed use, the BPTO will not allow post-filing submission of data to remedy this irregularity. The Applicant will need to prove that the specification as originally filed (with the originally disclosed data) suffices for carrying out the invention.

This requisite will be evaluated by observing whether the description in the specification provides clear evidence that the compound acts in the treatment of the target disease(s), e.g., the description of clinical assays, in vivo tests in association with in vitro tests, etc. Normally, the claimed subject matter cannot extend beyond the exemplified diseases and/or compounds.

As can be observed, in the case of patent applications in the chemical and pharmaceutical area, a more careful case-by-case technical analysis will be necessary due to the particular restrictions applied by the BPTO.

In case you need further information on this topic, we are at your disposal in our offices of Rio de Janeiro, São Paulo and Porto Alegre, as well as through: mail@kasznarleonardos.com