12 May 2017

The Honorable Luiz Otávio Pimentel
President
National Institute of Industrial Property
Ministry of Development, Industry and Foreign Trade (INPI)
Rua São Bento 1
CEP 20090-010
Rio de Janeiro, RJ
Brazil

Via email: saesp@inpi.gov.br

Re: IPO Comments on Draft Patent Examination Guidelines

Dear President Pimentel:

Intellectual Property Owners Association (IPO) submits the following comments on INPI's request for comments on the draft Guidelines for Patent Application Examinations, Aspects Related to the Examination of Patent Applications in the Area of Chemistry, published 17 March 2017 (the draft Guidelines).

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes about 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members.

IPO membership spans 50 countries. IPO advocates for effective and affordable IP rights and provides a wide array of services to its members, including: supporting member interests relating to legislative and international IP policies; analyzing current IP issues and providing information and education regarding those issues; and disseminating information to the public on the importance of intellectual property rights.

IPO appreciates INPI's effort to allow stakeholders the opportunity to provide comments on the draft Guidelines, which demonstrates that INPI is committed to transparency and public participation in the rulemaking process.

The draft Guidelines address several topics that were not expressly covered by the current Guidelines. We believe this is, in particular, an important step towards making the prosecution of patent applications in the chemical field more consistent, fair, and reasonable. IPO would like to highlight the initiative of creating guidelines concerning stereoisomers, polymorphs, and second medical use claims, which were previously considered controversial issues by certain practitioners and examiners in Brazil.

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IPO's comments are addressed solely to item 9.1 – New Medical Use. It is a significant improvement to have some guidance on the protection of second medical use inventions, particularly for innovative pharmaceutical companies. IPO believes, however, that the requirements established by the new guidelines are very restrictive and deviate from the current practice in other countries that are signatory of the TRIPS agreement.

Section 9.1.3 - Sufficiency of Disclosure states:

> Results of "*in vitro*" tests may show signs of new therapeutic use; however, *only "in vivo" tests are proof of new use,* ensuring that they are performed by an expert on the matter. It is worth noting that the "*in vitro*" test results often are not confirmed "*in vivo*", due to metabolic and pharmacokinetic aspects, among others, related to the drug's behavior within the organism. Thus, it is not always possible to extrapolate the results of "*in vitro*" tests to a real therapeutic application" (*emphasis added*).

IPO believes that the fact that only *in vivo* tests would be accepted as evidence of the new use is an inappropriate limitation on whether a second medical use is sufficiently disclosed. By imposing such limitation, INPI would not conform with the practice currently adopted by other major patent offices. For instance, according to the European Patent Office, showing a pharmaceutical effect *in vitro* can be sufficient if, for the skilled person, this observed effect directly and unambiguously reflects the therapeutic application or if there is a "clear and accepted established relationship" between the shown physiological activities and the disease.

IPO also notes the strict rule regarding the language of second use claims. For instance, under section 9.1.4, the following claims would not be accepted by INPI: "product X characterized by being used as a medicament" or "substance X for use in the treatment of medical condition Y". According to the draft Guidelines, such claims would render the subject matter for which protection is sought unclear and imprecise.

IPO maintains that a claim drafted as "product X characterized by being used as a medicament" should be accepted provided that the use of the product in a medicine is not previously known (novelty requirement) and that the claim involves an inventive step over any prior art. Similarly, a claim drafted as "substance X for use in the treatment of medical condition Y" should be accepted provided that substance X has not been previously known for treating the disease for which protection is sought (novelty requirement) and that such claim involves an inventive step over any prior art disclosing the use of X for treating one or more diseases or conditions.

Likewise, according to the draft Guidelines under sections 9.1.1 and 9.1.4, example 8, features related to the use of a particular compound, such as the therapeutic regimen (dosage, administration/application form, dosage range), cannot be claimed because such features define a therapeutic method. This limitation severely restricts the possibility of obtaining patent protection to important inventions and, again, deviates from the practice in other major jurisdictions.

We again thank INPI for permitting IPO to provide comments and would welcome any further dialogue or opportunity to provide additional information to assist your efforts in developing the draft Guidelines. We would also welcome any future opportunity to provide comments on the draft Guidelines in sections 2-8 that we were not able to address herein.

Sincerely,

Mark W. Lauroesch
Executive Director