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Sue Paredi
Executive Director

Zurich, 23 October 2025

To Mr. President Júlio César Castelo Branco Reis Moreira

National Institute of Industrial Property – INPI

Re.: Public Consultation No. 02/2025 on Examination Guidelines in Chemistry

Dear Mr. President,

I am writing on behalf of the International Association for the Protection of Intellectual Property (AIPPI) to express AIPPI's concern regarding the text proposed by the INPI through Public Consultation No. 02, published on July 29, 2025, for guidelines on the examination of patent applications. The proposed guidelines that are the subject of the consultation would have significant negative consequences for inventions in the pharmaceutical and biotech fields.

AIPPI

AIPPI is the world's leading non-profit association dedicated to the development and improvement of laws for the protection of intellectual property. It is a politically neutral and non-profit organization, headquartered in Switzerland, with more than 8,000 members in over 110 countries. The objective of AIPPI is to improve and promote the protection of intellectual property on both international and national bases. AIPPI pursues this goal by working towards the development, expansion, and enhancement of international and regional treaties and agreements, as well as national laws related to intellectual property.

AIPPI operates by conducting studies on existing national laws and proposes measures to achieve the harmonization of such laws at the international level. Where appropriate, AIPPI intervenes to advocate for the strengthening of intellectual property protection. The members of AIPPI are people actively interested in intellectual property protection on a national or international level.

They include lawyers, patent attorneys and trademark agents (both outside and in house counsel) as well as judges, academics, scientists and engineers. They also include corporations and other IP owners.

AIPPI's position on patents directed to second or further medical indications

There are three AIPPI Resolutions, adopted after an intense and comprehensive debate and voting process involving the global membership of AIPPI, that apply to the issue at hand.

In 2014, AIPPI Resolution Q238 addressed the issue of second medical use and other second indication claims. The preamble to the resolution observes that "*second medical uses may provide solutions to unmet medical needs and significant benefits to patients. They may require significant investment in research and development and represent socially, medically and economically valuable innovations*". AIPPI resolved *inter alia* that:

- as a matter of principle clearly reflected in the TRIPS agreement, patents should be granted without discrimination for any inventions in all fields of technology, including inventions relating to second medical uses;
- a second medical use should be patentable if it meets the patentability requirements of novelty, inventive step (non-obviousness) and utility or industrial applicability;
- patent eligible second medical uses may include the use of a known compound or substance in a new dosage regimen and a new therapeutic application of a known compound based on a different technical effect.

Resolution Q238 was silent on the burden of evidence required to obtain a second medical use claim.

In 2018, AIPPI Resolution Q266 addressed the issue of the use of post-filing data in support of inventive step/non-obviousness. In it, the AIPPI resolved *inter alia* that:

- AIPPI supports the use of post-filing data in support of inventive step/non-obviousness;

- In pre-grant proceedings, patent applicants should be able to support inventive step/non-obviousness of claimed subject-matter by relying on post-filing data showing at least one property or effect of the claimed invention, in particular in situations where the property or effect is already described in or is apparent from the parent application, either explicitly or implicitly.

In 2019, AIPPI Resolution Q267 addressed the issue of plausibility. In it, the AIPPI resolved *inter alia* that:

- There should be no stand-alone ground of patentability or validity based on plausibility.
- If credibility of the claimed invention is considered with respect to the requirements of patentability and validity, the threshold should be low and narrowly understood.
- The credibility threshold should be met when, based on the specification and common general knowledge, at least one of the following is satisfied:
 - The patent application contains, even implicitly, a convincing explanation as to why a technical effect may be obtained; or
 - It is credible for the person skilled in the art that at least one of the technical effects disclosed in, or derivable from, the application of the claimed invention may be obtained; or
 - The person skilled in the art has no serious reason to doubt that at least one of the said technical effects could work as described.
- Any effect claimed or relied upon for the assessment of the patentability and validity of the patent should be credible.
- The patentability and validity requirements should prohibit speculative claims, but a claim should not be considered speculative for the mere reason that the purported technical effect or the substantiation thereof is not explicitly mentioned in the specification. The number and nature of data and examples provided in the application should not be determinative in this respect.

AIPPI’s position on INPI Public Consultation No. 02, published on July 29, 2025

In addition to the general AIPPI view expressed above by reference to the resolutions formally adopted by the organization as a whole, three subject matter-specialist

committees of AIPPI independently reviewed and approved the position outlined in this letter (specifically, the AIPPI standing committees on Pharma, Biotech, and Patents).

AIPPI's concerns primarily pertain to the following aspects of the proposed guidelines:

- 1) *Features such as dosage amounts or ranges, routes of administration, patient groups, or timing of administration do not confer novelty to inventions related to new medical use (also referred to as "second medical use");*
- 2) *Results of in vivo tests must be present in the patent application at the time of filing for inventions related to new medical use (also referred to as "second medical use"); and*
- 3) *The post-filing of data in relation the inventions directed to second (or further) medical indications would not be allowed.*

As an overarching point which relates to each of the three points noted above, AIPPI observes that the existing patentability requirements (in particular, novelty, inventive step and sufficiency) already serve as an effective quality control measure that is already well-understood both nationally and internationally, and supported by a wealth of experience and case law in their application. In AIPPI's view the current tests and requirements for patentability of an invention (which apply across all fields and industries) already carefully and appropriately balance the relevant competing policy considerations and protect against speculative or insufficiently supported claims in a way that allows for nuance and consideration of the specific facts, circumstances and state of knowledge in the relevant field in question. The creation of additional rules-based, field-limited and indiscriminatory technical obstacles to obtaining a patent and/or a blanket ban on patenting in certain fields altogether is not only unnecessary in the circumstances but would also be contrary to the basic principles of patent law, chill investment in the field in Brazil and ultimately harm Brazilian patients and the public.

In addition, specifically in relation to point 1) above, AIPPI notes that inventions which are based on insights in relation to dosage amounts or ranges, routes of administration, patient groups, or timing of administration can represent significant

innovations which may result in improved treatments, greater efficacy and safety, and/or lower cost of treatment. This ultimately leads to a better quality of life for patients suffering from a disease or disorder. Such benefits are often the outcome of significant investment in long-term research and clinical trials, involving extensive technical skills and knowledge. Such inventions can therefore be true innovations and advancements in the art. For this reason, pursuing such inventions should be encouraged, and such inventions should be eligible for patent protection.

As regards point 2), requiring *in vivo* test data in any patent application for a new medical use invention would create a new hurdle that is not present for any other field of art. The requirement for a specific data/test type in case of inventions directed to second (or further) medical indications would be contrary to TRIPS and the principle that patents be granted without discrimination in all fields.

Further, introducing a requirement for a specific type of data/test in the case of inventions directed at second (or further) medical indications would be contrary to the basic premises of patent law. Patent law already requires that a specification disclose information and data sufficient to convince a person of skill in the art that the invention works and to enable them to perform the claimed invention. In no other field, nor in most other jurisdictions, is there a requirement that evidence of the working of an invention be shown by a prescribed type of data/test.

The requirement for *in vivo* testing data would also set Brazil apart from most other jurisdictions; *in vivo* testing is not a requirement for inventions directed to secondary medical applications in most other jurisdictions.

Certainly, it is agreed that an invention directed to a second (or further) medical indication should be plausibly and convincingly supported in the specification as filed. In many cases however, this can be done without the need for *in vivo* data. In some specific cases, depending on the disease state, the knowledge in the art, and the compound used for the treatment, *in vivo* data might be needed to convince a person of skill in the art of the plausibility of the alleged technical effect of the claimed invention. But other times, it might be sufficient to use a well understood predictor of utility, such as an established cell culture model, assay, or test. Indeed, sometimes the discovery of a new correlation between a disease and a target molecule might be sufficient to lead a person of skill in the art easily and without difficulty to the new use, and might convince a person of its utility.

By denying, on principle, the patentability of inventions related to dosage amounts and ranges, routes of administration, patient groups, or timing of administration, and by creating an excessive burden concerning technical demonstration for applications related to new medical use, the INPI would discourage an entire line of scientific research and innovation which is aimed at bringing better and more tailored medicines to patients.

As regards 3), submission of additional confirmatory data after filing, permitted for all other technical areas, should also be permitted for second medical uses where the second medical use is already plausibly disclosed in the application as filed.

The proposed guideline text would prohibit the submission of any data after the filing of a patent application related to a second (or further) medical indication, which will undeniably jeopardize numerous patent applications, including applications already filed with INPI, in various technical fields, representing a major setback for the Brazilian IP system.

Given these concerns, we believe that pursuing the currently proposed guidelines and maintaining the public consultation in respect of the guidelines as proposed, may cause serious harm to the innovation environment in Brazil.

Therefore, we respectfully request that the INPI cancels the present consultation, so that the matter may be discussed more broadly and balanced with the society, industry and academy.

We hope this request is fully considered and we remain at your disposal to contribute to future technical and legal discussions on this matter.

Sincerely,

A handwritten signature in blue ink, appearing to be 'Sue Paredi', written over a light blue circular stamp.

Sue Paredi

Executive Director AIPPI