

Brazilian PTO Signals Potential Patent Reform and Introduces New Guidelines on New Use of Known Products

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Authors

Ana Cristina Müller, D.Sc.

Lilian Ghitnick Arcalji

Catarina Alonso Guimarães

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In 2026, Brazilian Industrial Property Law ("LPI"—*Lei de Propriedade Industrial*) marks its 30th anniversary, prompting renewed discussion about possible updates to the country's industrial property framework. The INPI (*Instituto Nacional de Propriedade Industrial*), Brazilian Patent and Trademark Office, recently published its report *Proposals for Improving the Industrial Property Law – LPI (9.279/1996)*, prepared by the LPI Review Working Group as a contribution to discussions on potential amendments to the legislation.

The report compiles proposals submitted by INPI staff and comments from the relevant technical divisions, covering patents, trademarks, industrial designs and geographical indications. In the patent field, one of the proposals considered by the Directorate of Patents, Computer Programs and Integrated Circuit Topographies ("DIRPA"—*Diretoria de Patentes, Programas de Computador e Topografias de Circuitos Integrados*) concerns the revision of the rules governing non-patentable subject matter and subject matter not considered to be inventions, particularly with respect to the protection of parts of living organisms, biological sequences, and extracts.

Currently, Articles 10 and 18 of the Brazilian Industrial Property Law provide, respectively, that "*the whole or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germplasm of any natural living being, as well as natural biological processes*" are not considered inventions or utility models, and that "*the whole or part of living beings, except transgenic microorganisms that meet the three patentability requirements [...] and are not a mere discovery*" are

not patentable.

Any legislative review of these provisions could have significant implications for research- and development-intensive industries, particularly biotechnology, chemistry, pharmaceuticals, agribusiness and the life sciences. The report nevertheless highlights the need for broad public debate on the matter, given its technical, legal and economic implications.

No legislative timetable has yet been established for any amendment of the LPI. Even so, the publication of the report suggests that INPI is actively considering possible updates to Brazilian intellectual property framework, particularly in areas where the current legislation may no longer fully reflect the needs of companies, universities and research institutions engaged in R&D&I activities.

Separately, and as part of this broader review of the patent system, **Administrative Order INPI/PR No. 80, dated June 29, 2026**, was published in Industrial Property Gazette ("RPI") No. 2895 of June 30, 2026. This Administrative Order establishes the rules governing the examination of patent applications in the field of chemistry, pursuant to the new Chapter 9 of the Guidelines for the Examination of Patent Applications in the Field of Chemistry, which is dedicated to new uses of known products.

The revised Chapter 9 is intended to increase transparency around the criteria applied in examining patent applications related to the new uses of known products and promote a more consistent and predictable examination process.

In addition to providing examples of claim formats that will and will not be accepted, the new chapter also specifies that, in order to satisfy the sufficiency of disclosure requirement, the specification of a patent application directed to a new use of a known product should preferably include *in vivo* test data. In cases where *in vitro*, *ex vivo*, or *in silico* tests are submitted, but their results do not allow the claimed therapeutic activity to be established unequivocally, supplementary information may be submitted, provided that the specification as originally filed already demonstrates that the alleged therapeutic activity is real rather than merely speculative.

The Guidelines also address second medical use applications involving known products that are defined broadly, for example by reference to a chemical class. In such cases, only compounds that have actually been tested will be considered sufficiently disclosed. Where the compounds are defined using Markush formulae, applicants must demonstrate the claimed therapeutic effect for at least one representative compound from each chemical class represented by the various substituents.

Together, these developments reflect the INPI's efforts to make patent examination more consistent and predictable, particularly in technically complex and commercially important fields. While any amendments to the LPI would require legislative action, the release of both the proposals report and the new Guidelines related to the new use of known products suggests a willingness to reassess aspects of Brazilian patent framework and consider potential updates to the current system.

Our Intellectual Property team is monitoring these developments closely. Please contact us if you would like to discuss their potential implications for

protecting, managing, and commercializing innovation assets in Brazil.

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Professionals who combine legal insight and market perspective



Ana Cristina Müller, D.Sc.



Lilian Ghitnick Arcalji



Catarina Alonso Guimarães