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Relevant Patent News: Significant Change in the Patentability Examination of Chemical-Pharmaceutical Inventions

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Today, Joint Resolution RESFC-2026-1-APN-INPI#MEC was published. This resolution, which was signed by the Minister of Health, the Minister of Economy, and the President of the National Institute of Industrial Property (INPI), repeals the Joint Resolution of the former Ministry of Industry No. 118, the Ministry of Health No. 546, and INPI No. 107 dated May 2, 2012, which approved the "Guidelines for the patentability examination of patent applications on chemical-pharmaceutical inventions". The new regulation restores to INPI its exclusive competence to determine the patentability of this type of invention on a case-by-case basis, in accordance with Patent Law No. 24,481, and establishes a transitional protection mechanism for those already commercializing pharmaceutical products covered by patents that may be granted under the new regime.

What Changed?

Aspect	Before (Joint Res. 118/546/107 of 2012)	Now (Joint Res. RESFC-2026-1)
Applicable regulatory framework	Patent Law + specific guidelines of Joint Res. 118/546/107 of 2012	Exclusively the Patent Law (No. 24,481)
Examination criteria	Restricted by guidelines that limited the patentability of chemical-pharmaceutical inventions	Case-by-case analysis by INPI, in accordance with the general requirements of novelty, inventive step, and industrial application
INPI's competence	Conditioned by interministerial directives	Full and exclusive authority to evaluate patentability
Protection for third-party marketers	Not provided	Holders of patents granted under the new regime may not prevent the commercialization of pharmaceutical products that were already being marketed locally by third parties as of the



		effective date, nor require compensation
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What Is the Rationale?

The new resolution considers it appropriate not to restrict INPI's natural competence to examine patent applications, and that the strengthening of intellectual property rights promotes innovation and generates conditions of predictability and legal certainty that facilitate timely access to new medicines.

When Does It Take Effect?

The resolution enters into force as of the date of its publication in the Official Gazette (Art. 3).

What Are Its Practical Implications?

INPI will be able to grant patents on chemical-pharmaceutical inventions that under the previous regime could have been rejected, applying exclusively the requirements of the Patent Law. This is especially relevant not only for applications that are currently pending, which could obtain a favorable result under the new examination criteria, but also for the expectations of protection of chemical-pharmaceutical inventions in Argentina through the country's existing patent system.

We recommend that holders of pending pharmaceutical patent applications evaluate the impact of the repeal on their ongoing proceedings. In turn, third parties that commercialize products that could be covered by pending patents must adequately document their commercialization as of the regulation's effective date, in order to prove eligibility for the exception under Article 2.