Expert Contributor

Mexico´s Pharmaceutical IP Crossroads: Reform Rights and Wrongs.

By Alejandro Luna F.
Mon, 06/01/2026

Q: How has intellectual property evolved from being a legal safeguard to becoming a strategic growth engine for pharmaceutical and life sciences companies in Mexico?

A: We are in a period of genuine transformation. Some changes stem from international commitments Mexico has undertaken through trade treaties with substantial IP chapters; others emerge from a domestic agenda. What is encouraging is that Mexico now has a national intellectual property policy shaping the regulatory framework, not just international pressure driving the reform.
We are at a real crossroads: April brought new amendments to the Federal Law for the Protection of Industrial Property, the corresponding regulation alongside important revisions to the Health Law Regulations with direct implications for intellectual property and clinical data protection.

Q: How have these reforms impacted your work, and do you see them as complete or are there gaps that still need to be addressed?

A: My feelings are mixed. There are elements worth welcoming: the adoption of inclusive language throughout the legislation and the adaptation of processes and procedures to digital environments are both positive steps.
On the other hand, the reform grants IMPI expanded faculties in areas that remain poorly defined, particularly technology transfer. Assigning the authority roles in mediation, arbitration, and expert opinions raises serious impartiality concerns, given that IMPI simultaneously holds registration and enforcement powers over the very rights it protects. There is already a law regulating technology transfer promotion; it should be governed by separate rules and public policy, yet everything was folded into IMPI's mandate.
What concerns me most is the self-imposed one-year deadline for granting patents. Faster sounds better from the outside, but patent quality is not simply a function of time. As far as I know, no country in the world operates under a one-year granting window, as international treaties set five years as a standard maximum, failures to the five year term, could derive in patent term adjustments.
The reform mentions hiring 400 new examiners, but that has not materialized. Where is the physical space? Where is the training in patent law and substantive examination? If those pieces come together, the deadline becomes achievable. If they do not, officials will be issuing patents by obligation rather than conviction, which undermines the entire purpose of the system.

Q: Do you think this creates more uncertainty, or is it more of a "wait and see" situation?

A: It is under testing. If patents are issued out of obligation, because officials face personal liability for missing the deadline, rather than out of rigorous substantive examination, the quality of those grants will suffer. That is the core risk. It also makes the patent life compensation mechanism pointless. Mexico fought hard during USMCA negotiations to not be obliged to grant patent term adjustmets of the patent after five years of prosecution, and now the country self-imposes a one-year granting window that goes beyond any USMCA obligation. That is a paradox no one has adequately explained.

When I started practicing 30 years ago, IMPI took six to eight years to grant a patent. Today it takes around two to three, without any decree mandating shorter terms or reducing office actions. That improvement happened organically. Why legislate an aspiration as a legal obligation?

Where the backlog actually exists, in infringement and nullity procedures that drag on for five or six years before IMPI, no deadlines were reduced, no time limits were imposed on IMPI to resolve cases, and the pending issue of damages and losses at IMPI was left untouched. The reform applied pressure where it was least needed and left the structural problem intact.

Q: Since the reform is so recent, when will we start seeing the real impacts?

A: The early signals will come from the quality of the official actions that IMPI issues. There was also an IMPI decree, separate from the law itself, reducing substantive office actions from four to two, likely anticipating the one-year goal. We will see how those actions hold up technically, whether the 400 examiners are actually hired, and whether applications filed from April onward are genuinely resolved within a year, or whether the process simply becomes a production line, or worse, generates complaints against individual officials.

Q: What would a reform that genuinely incentivizes innovation in Mexico look like?

A: There is a genuine and positive intention behind these reforms: to incentivize innovation and increase the number of patent applications from Mexican inventors and companies. That goal is commendable. However, reducing granting times and compressing the substantive examination is not the path to achieving it. Real innovation requires economic conditions, tax incentives, accessible financing, and structured collaboration between the private sector, universities, and research centers.

Patents cannot be granted based on nationality or commercial potential; that is prohibited under international treaty. Patentability requires inventive step, novelty, and industrial application, and those standards apply equally to all applicants. Female inventors, for instance, represent less than 2% of patent applicants in Mexico. If the goal is to raise participation among underrepresented inventors, the answer is targeted incentives: green patent tracks, tax benefits for research centers that hire women, accessible and affordable expert support for first-time applicants. That is how structural change happens. A provisional patent application mechanism will not move that needle.

I predict it will be very little used. A pool of affordable patent experts helping inventors file complete applications from the start would serve the same population far more effectively.

Q: How do you see the current landscape for biosimilars in Mexico?

A: There have been very recent changes to the Health Law Regulations, touching three areas: the patent linkage system, clinical data protection, and the regulation of biologics and generics. This reform is much more clearly USMCA-driven than the industrial property one.
On linkage, additional elements were introduced to improve communication between IMPI and COFEPRIS and prevent sanitary registrations from being granted in violation of active patents. An opposition mechanism was included, but it is unworkable in practice. The information COFEPRIS publishes is limited to the generic name, the applicant, the filing date, and the pharmaceutical form. A patent holder cannot mount a meaningful opposition on that basis, as it is opposing blindly. The system effectively reverses the burden, telling rights holders to monitor an incomplete public list rather than providing direct notification as USMCA requires. That, in my view, is a clear treaty violation. It also raises constitutional concerns around due process and the right to be heard.
On clinical data protection, a five-year protection period for innovator data was established, but without clarifying how that protection operates in practice; it does not address indirect reliance. If interchangeability has already been demonstrated using originator data, those studies have effectively been relied upon. That gap matters. More significantly, biologics were not given differentiated protection. The clinical development of a biologic is substantially more complex, time-consuming, and expensive than that of a small molecule; greater protection is justified and the regulation does not provide it. Orphan drugs and new indications were also left out entirely. These omissions reduce the incentive for innovators, domestic or international, to develop or bring new biologics to Mexico.

Q: Beyond the reforms we have discussed, where do you see Mexico aligning well with global IP and regulatory best practices?

A: One area worth highlighting is COFEPRIS's growing practice of recognizing decisions from foreign agencies such as the FDA and EMA. Regulatory reliance, done with the appropriate safeguards, is not a concession, it is a practical use of existing rigor. The same logic applies in patents through the Patent Prosecution Highway: if a patent has already been substantively examined in another jurisdiction and the claims align, the Mexican examiner reviews that work rather than starting from zero. There is nothing wrong with building on what has already been done carefully, as long as our own standards and local particularities are verified in the process.

Q: How do you see this year, and what is your goal for 2026?

A: Despite the areas of opportunity these reforms reveal, there is a genuine intention to improve the system and make it more competitive. The task now is to learn from these reforms and use them strategically. Clinical data protection, for instance, is not exactly what we advocated for, but it exists now. That is a foundation to build on.

The current administration has shown more openness to technical dialogue than its predecessor, and we intend to use that. The next priority is pushing for greater protection for biologics and closing the gaps this reform left open.

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