

Craig Metcalf of Kirton McConkie reviews the findings in the case that has solidified the enablement requirement for pharmaceuticals in the US patent system.







From past to present: shifting interpretations of The Mexican Patent Office on divisional applications

Sergio Olivares, Daniel Sánchez and Rommy Morales of OLIVARES compare the new approach to divisional applications implemented with the Federal Law for the Protection of Industrial Property 2020 with the old to provide guidance for proceeding.

he coming into effect of the Federal Law for the Protection of Industrial Property (FLPIP) on November 5, 2020, was a turning point that brought substantial changes to Mexico's Industrial Property law, particularly concerning the practice with respect to divisional applications, marking the beginning of a new approach in this field.

Divisional applications play a crucial role in intellectual property protection by allowing applicants to pursue distinct inventions separate from those claimed in the initial application and any prior divisional applications. In this regard, it is important to consider that Mexican law only recognizes divisional applications, unlike the US law where continuation or continuation in part applications exist as well.

Before the FLPIP was enacted, the submission date of a divisional application was one of the most important points to bear in mind. Divisional applications could be filed as long as the parent case was still pending, regardless of whether said parent case was a divisional application or whether the initial application was pending or had already been granted.

Nonetheless, the implementation of the current law imposed new constraints and additional requirements for applicants to contemplate when filing one or more divisional applications, which directly impact the two types of divisional applications recognized by IMPI, those voluntarily submitted, and those submitted in response to a lack of unity of invention objection.

Voluntary divisional applications

Voluntary divisional applications are commonly used

If the patent application encompasses multiple inventions not linked by the same inventive concept, the applicant can even file a single divisional application pursuing several of these inventions.



when the applicant wishes to pursue a different scope, seek protection for a different invention, or simply as a strategy to maintain the pendency of the patent family.

Unlike the abrogated law, which was silent on voluntary divisional applications, the current law does so by stating that a pending initial patent application can be voluntarily divided. However, this provision does not extend to divisional applications.

Voluntary divisional applications can be submitted at any time and up until before the grant fee payment or the issuance of the notice of denial, with no limit imposed on the number of divisional applications that may be submitted. Taking this provision into consideration, it becomes possible to submit multiple voluntary divisional applications, each directed to a different invention or group of inventions, all directly derived from the initial application while it remains pending.

Divisional applications submitted by request of IMPI

Mexican legislation stipulates that a patent application should refer to one invention or a group of inventions sharing a single inventive concept. This requirement of unity of invention involves having a clear relationship between the essential technical features present in the invention or group of inventions, contributing to the state of the art.

During the substantive examination process, if it is found that the patent application fails to comply with the unity of invention requirement, IMPI issues an office action requesting the applicant to limit the claims to the main invention and submit one or more divisional applications for the remaining inventions.

73

CTC Legal Media THE PATENT LAWYER

The first invention pursued in the claims is considered the main invention, which according to the current law should be examined on the merits. However, in practice, IMPI usually allows applicants to claim the invention of interest, even if it does not always correspond to the main invention.

Résumés

Sergio Olivares joined OLIVARES in 1987 and has been practicing intellectual property law for more than three decades. He has been a partner since 1994 and Chairman of the firm's Management Committee since 2009. He is proficient across all areas of IP law, but works most closely with the firm's Patent Group. Sergio is highly recommended by leading industry publications and directories as a leader in IP. He has been integral to OLIVARES' expansion into new and innovative practice areas; has been at the helm of cases that are helping to shape the standard for evaluating inventive step and novelty for pharmaceutical patents; and was involved in a landmark Supreme Court case that changed the landscape for unfair competition enforcement in Mexico. Sergio received his J.D. from the Universidad Intercontinental in 1991 and graduated from the Franklin Pierce Center for Intellectual Property in 1993.

Daniel Sánchez joined OLIVARES in 2000, became a partner in 2011, and co-chairs the firm's Litigation and Patent Teams. He is one of the leading intellectual property and administrative litigators in Mexico and is recognized by industry rankings and publications including Chambers Latin America, IAM Patent 1000, and WTR 1000. As one of the few regulatory and administrative litigation experts in Mexico, Mr. Sanchez guided the development and implementation of a revolutionary and proprietary software system that replicates the drug naming and labeling approval process within COFEPRIS, Mexico's health ministry. This drastically improves the accuracy of advice about whether clients' marketing authorizations can and will be approved. He also has led Olivares' team in obtaining alcoholic beverage advertisement approvals from COFEPRIS, has authored various articles on IP and Life Sciences-related matters, and he has lectured on IP topics in both national and international forums.

Rommy Morales boasts over 16 years of experience in intellectual property, with a specialization in patent prosecution, IP litigation, and plant variety protection. She is renowned for accurately identifying clients' needs and subsequently developing and implementing strategies tailored to the protection of their industrial property rights.

Rommy provides technical and legal advice to national and international clients in the pharmaceutical, biotechnology, and chemical industries. Her advice covers the preparation, filing, prosecution, granting, and enforcement of patents, including patentability and validity opinions, as well as freedom-to-operate analyses.

In her role, Rommy Morales supervises the team responsible for filing and prosecuting patent applications. Owing to her distinguished reputation as a biologist and her extensive experience in the field, she also leads the department dedicated to plant variety protection in Mexico.

Rommy has participated in numerous legal proceedings related to life sciences, including litigation cases involving pharmaceutical products of significant commercial interest.

When faced with the unity rejection, applicants have several routes to consider. One option is to maintain the claims focused on the invention of interest while eliminating the remaining claims. Applicants have the opportunity to pursue these eliminated claims through one or more divisional applications, which must be submitted along with the response to the office action objecting to the unity of invention.

If the patent application encompasses multiple inventions not linked by the same inventive concept, the applicant can even file a single divisional application pursuing several of these inventions. This would trigger a new unity of invention objection, thereby providing a new opportunity to submit cascade divisional applications in the future.

Alternatively, applicants can choose to submit arguments to persuade the examiner that the claimed invention(s) are indeed related by the same inventive concept. Another viable approach is to make amendments to the claims, ensuring compliance with the unity of invention requirement without the need to submit divisional applications.

Restrictions for subject-matter that can be pursued in divisional applications

At the time of submission, every divisional application must include the specification, claims, drawings, and sequence listings (where applicable), along with the official filing fee payment. These divisional applications are not allowed to introduce new subject matter or broaden the scope of the original case.

Divisional applications must pursue a different invention from the one claimed in the initial application and any other previous divisional applications. While the law does not define what is understood by a "different invention", the law does set a clear boundary: a patent will not be granted for subject matter that is already protected by another patent or for non-substantial variation, regardless of whether the applicant remains the same.

As a consequence, IMPI could reject a divisional application seeking protection for a non-substantial variation of the subject matter claimed in the initial application or applications within the same family, although the claimed matter is not identical, but there is overlapping subject matter.

Another significant limitation found in the current law is that once an invention or group of inventions is no longer claimed when a division takes place, it cannot be claimed again in the initial application or the one that triggered the division.

It is important to highlight that these limitations apply not only to patent applications but also to utility model and industrial design applications.

74 THE PATENT LAWYER CTC Legal Media

Cascade divisional applications

Before the entry into force of the LFPPI, cascade divisional applications were accepted by IMPI as long as the immediate predecessor application was still pending, regardless of the status of the initial application or the generation of the immediate predecessor (e.g., first-generation, second-generation, etc.).

Nevertheless, a substantial restriction was incorporated into the current law, as it stipulates that divisional applications cannot consist of the division of other divisional applications unless they are deemed appropriate by IMPI or filed in response to a unity objection. Failure to meet this condition results in the application not being recognized as a divisional, depriving it of the legal filing date or priority rights of the application from which it seeks to derive. Instead, it will be treated as an independent application filed on the date it was submitted to IMPI, which would finally lead to the refusal of the application due to lack of novelty in view of the publication of the initial patent application.

Regardless of the major limiting factor discussed above, the transitional articles of the new law provide an exception. They state that patent, utility model, or industrial design applications that were pending at the time of the law's enactment would continue to be prosecuted in accordance with the provisions in force at the time they were filed

Considering the above, the limitations imposed on cascade divisional applications should apply solely to initial (root) applications filed on or after November 5, 2020. In contrast, any applications that remained pending and were filed before this date should be prosecuted according to the provisions outlined in the preceding law.

However, the authorities' interpretation of the aforementioned legal provisions has been uncertain, as IMPI has adopted a series of varying criteria over time. This has led to a shifting land-scape for divisional patent applications. The following section will explore the evolution of IMPI's interpretation and the impact it has had on the prosecution of cascade divisional applications.

Analyzing the journey of cascade divisional applications: where do we stand now?

Despite the provisions contemplated of the new law and the provisions established in our constitution that indicate that laws cannot be applied retroactively to the detriment of the applicant, since November 5, 2020, and for approximately one year thereafter, IMPI rejected voluntary cascade divisional applications, even those that derived from applications prosecuted under the previous law.

These cascade divisional applications were not recognized as divisional patent applications but considered as independent applications



Sergio Olivares



Daniel Sánchez



Rommy Morales

under the premise that the prosecution of their initial parent case had already been concluded. In other words, divisional applications that derived from an initial application filed under the previous law were being analyzed by IMPI according to the new law just because they were filed after November 5, 2020, instead of using the law applied to the initial application.

Given the significant impact of this uncertain criteria on Mexico's patent system, OLIVARES, in conjunction with various affiliated associations, promoted a shift in criteria for proper interpretation of the legal framework by the authority. As a result of these efforts, in 2022, IMPI began accepting cascade divisional applications deriving from those filed under the previous law.

Unfortunately, this revised approach did not last long, since recently, IMPI reverted to its original position, dismissing voluntarily submitted cascade divisional applications once again. This time, the authority is grounding its arguments on a court decision, asserting that a divisional application cannot be accepted once the prosecution of the parent application has concluded. As a consequence, litigation on these matters will be necessary.

This prevailing scenario could have a profound impact on the patent landscape since it raises the potential for initiating legal actions by third parties seeking the nullity of cascade divisional applications that had been previously accepted by IMPI. Parties may challenge the validity of these divisional applications based on the IMPI's interpretation of the law. Moreover, it could set a precedent, questioning the legitimacy of other cascade divisional applications, even those granted under different interpretations of the law.

Facing this uncertainty of IMPI's criteria, predicting the future of divisional applications becomes quite challenging. Therefore, it is essential to stay aware of this evolving patent landscape. This will enable patent holders to adapt and formulate appropriate strategies for the timely filing of divisional applications.

Contact

OLIVARES

Pedro Luis Ogazón 17, San Ángel, Álvaro Obregón, 01000 Ciudad de México, CDMX, Mexico

75

Tel: + 52 (55) 5322 3000 www.olivares.mx

CTC Legal Media THE PATENT LAWYER