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Improvement to the patent term extension system for drug patents in China



Eddie Zheng and Dawn Chen of Corner Stone & Partners examine the dual impact of China's patent term extension system on pharmaceutical R&D and innovation and offer policy recommendations for its improvement.



Navigating divisional application strategies in Mexico

Sergio L. Olivares Sr. and Mauricio Samano of OLIVARES review the Federal Law for the Protection of Industrial Property, highlighting a significant gap in the legislation stemming from the absence of regulations governing divisional applications.

Divisional applications are an excellent way to protect additional embodiments of an invention. In many fields, and especially in the pharmaceutical industry, divisional applications are used to robustly protect a patent portfolio. Mexico is not an exception; for many years, patent owners have filed numerous divisional applications, either voluntarily or as a result of a lack of unity objection.

In 2020, the Federal Law for the Protection of Industrial Property (FLPIP) came into force in Mexico, containing several new limitations on filing divisional applications. These limitations, in addition to the current lack of specific regulations in Mexico's IP law, have created an environment of uncertainty for applicants regarding the most effective strategy to ensure robust protection of their patent portfolios.

Divisional applications before November 5, 2020

Before the FLPIP took effect on November 5, 2020, the applicable law was the former Intellectual Property Law (IPL). The IPL only specifically addressed the scenario of filing a divisional application as a result of a lack of unity objection; however, in practice, Examiners also accepted voluntary divisional applications if they were filed at any time during the prosecution of the parent case and before the payment of the grant fees. There was no limit on the number of voluntary divisional applications that could be filed, and there was no limitation on filing cascade divisional applications. It was frequent to see fourth and even fifth-generation divisional applications.

The Mexican Institute of Industrial Property's (IMPI) practice for voluntary divisional applications



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was supported in Article 4 G (2) of the Paris Convention which says that *"The applicant may also, on his own initiative, divide a patent application and preserve as the date of each divisional application the date of the initial application and the benefit of the right of priority, if any. Each country of the Union shall have the right to determine the conditions under which such division shall be authorized."*

This practice continued for many years and was viewed as positive by most patent owners.

Limitations to divisional applications present in the FLPIP

Cascade divisional applications

Article 100 of the FLPIP is the main article regulating the filing of divisional applications in Mexico. It contemplates the possibility of filing divisional applications either voluntarily or as a result of a lack of unity objection. The time limit for filing any voluntary divisional is before the payment of the grant fees of the parent case or before receiving a rejection. In the case of divisional applications that are filed as a result of a lack of unity objection, these must be filed before or at the same time as the response to the office action that raised the lack of unity objection.

Article 100 also specifically states that voluntary divisional applications deriving from divisional applications will no longer be allowed. The only way to file cascade divisional applications is if the IMPI requires further division due to a lack of unity objection.

It is clear that this limitation applies to patent applications (either national phase PCT applications or applications filed through the Paris Convention) that were filed in Mexico on or after November



5, 2020, and in theory, should not apply to voluntary cascade divisional applications that derive from a first parent case that was filed before November 5, 2020. However, in late November of last year, the Regional Circuit Plenum resolved a legal controversy that arose from conflicting rulings by two circuit courts. The Plenum ruled that if the original parent case is no longer being prosecuted at the time the new divisional application is filed, the new application must be prosecuted under the new law. Therefore, the restrictions under the FLPIP are now applicable to cascade divisional applications that derive from a first parent case that was prosecuted under the previous law. This decision constitutes binding jurisprudence at the circuit court level; however, it can be overturned by the Supreme Court.

This current scenario requires the redefinition of divisional application strategy in Mexico, and under this current scenario, we have the following options:

- To file all the divisional applications of interest directly from the first parent case.
- To file a single divisional application that contains claims that lack unity of invention, and in this way, can file a further divisional application once the IMPI issues a lack of unity objection in the divisional application.

It is worth mentioning that we have seen some isolated cases in which Examiners require applicants to file a divisional application for each of the identified inventions directly from

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Résumés

Sergio L. Olivares Sr. joined OLIVARES in 1987 and has been practicing intellectual property (IP) law for over three decades. He has been a partner since 1994 and Chairman of the firm's Management Committee since 2009. He is proficient in 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; he has been at the helm of cases that are helping to shape the standard for evaluating inventive step and novelty for pharmaceutical patents.

Mauricio Samano works in the patent department of the OLIVARES firm. His work mainly focuses on prosecuting chemical, biotechnological, and pharmaceutical patent applications, as well as providing technical opinions regarding patent infringement. Mauricio has experience in conducting state-of-the-art searches and drafting patent, utility model, and industrial design applications. Additionally, he is a member of the International Patent Law and Trade Committee, as well as of the Latin American Practice Committee of Intellectual Property Owners (IPO) organization.

the parent case, which, from our perspective, is incorrect. For example, we have seen instances in which the Examiner issues a lack of unity objection in the parent case and identifies four inventions and obligates the applicant to select the first identified invention to remain in the parent case and to file three separate divisional applications for the other three identified inventions instead of a single divisional containing all the other three identified inventions. We disagree with this criterion because it is contrary to Article 100 of the FLPIP, which leaves open the possibility for applicants to file a cascade divisional application in cases where the matter pursued in a divisional application lacks unity of invention.

From our perspective, applicants should not be forced to file a divisional application for each of the remaining inventions directly from the parent case because applicants often don't have a clear idea of the specific matter that is of commercial interest. Thus, applicants should be able to file a single divisional application directed to all the non-elected inventions and have more time to decide which scope is of most interest for them once the IMPI issues a first office action in the divisional with a lack of unity objection.

Limitations on matters to pursue in the parent case and subsequent divisional applications

Article 113 of the FLPIP states that when an application lacks unity of invention, the Examiner will consider the main invention as the one first mentioned in the claims, evaluating the compliance of the remaining patentability requirements (novelty, inventive step, etc.) for this invention only. In this case, the IMPI will require the applicant to limit the claims to the main invention and file the corresponding divisional application(s).

Thus, based on Article 113, Examiners are now obligating applicants to limit the claims of the parent case to those of the invention which is first mentioned in the claims and do not allow applicants to limit the claims of the parent case to any of the other subsequently identified inventions. In cases where the applicant is only interested in protecting one of the other identified inventions, Examiners request that applicants file a divisional application with the claims of interest and abandon the parent case. However, Article 113 does not explicitly state that the applicant is obligated to limit the scope of the parent case to the invention that is first mentioned in the claims, and that none of the other identified inventions can be claimed in the parent case. With this interpretation, the IMPI is making an arbitrary decision and forcing the applicant to claim in the parent case an invention that, at that time, may no longer be of commercial interest to them. Unfortunately, the lack of specific regulations and guidelines for Examiners leaves enormous grey areas in

“**File a voluntary amendment before substantive examination begins to assure that the invention that is first mentioned in the claims is the one of most commercial value for the applicant.**”

domestic law that give rise to this unfortunate criterion.

In abundance of caution, and if applicable, one possible strategy is to file a voluntary amendment before substantive examination begins to assure that the invention that is first mentioned in the claims is the one of most commercial value for the applicant. We understand that in most cases, the applicant does not have that information when national phases are filed in each country of interest. Therefore, it is essential to consider that in Mexico, the first office action is typically issued between two and three years after the filing date, which provides some time for the applicant to file this eventual voluntary amendment.

Double patenting

Unlike the IPL, the FLPIP outlines specific provisions regarding double patenting. However, these provisions are very vague, leaving a considerable grey area for interpretation. The specific articles that regulate double patenting are Articles 50 and 101, which mention the following:

“During substantive examination and in the granting of rights, IMPI shall look out for the public domain and prevent double patenting of the same invention” (Article 50) and “No patent will be granted to matter that is already protected by another patent, or which essential technical characteristics are a non-substantial variation of the matter protected by another patent, even when the applicant is the same in both” (Article 101).

Since the FLPIP does not define what constitutes a “substantial variation,” Examiners are issuing double patenting objections in many divisional applications that only have a minor scope overlap with the claims granted in the parent case that originated the divisional application, and which are directed to different subject matter.

We have seen cases where Examiners also raise double patenting objections when a divisional application includes matter that was initially claimed in the parent case but was carved out during prosecution and included in the divisional application. This interpretation is contrary to international patent practice and completely undermines the meaning of what a divisional application entails in many jurisdictions worldwide.

As a general strategy, it is advisable to minimize scope overlap between the claims of the parent case and those pursued in the divisional application. Further, point out to the Examiner why the matter pursued in the divisional application can be understood as a modification or change to the matter protected in the parent case, which is significant in its operation, to such an extent that this variation resolves a technical effect.

Conclusion

While there have been notable advancements

in Mexican patent prosecution, such as the introduction of mechanisms like the Parallel Patent Grant (PPG) and Accelerated Patent Grant (APG) for fast-tracking applications with granted US counterparts, as well as the recognition of patent term adjustments (PTA) for undue delays caused by IMPI, critical gaps remain — specifically, the absence of regulations under the FLPIP, particularly regarding divisional application practices. The urgent publication of these regulations is essential to provide legal certainty, enhance procedural transparency, and address longstanding concerns. Resolving this issue could play a significant role in helping Mexico move off the USTR's Special 301 Report Priority Watch List, where it remains in part due to these regulatory deficiencies.

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