



Expert Contributor
By Alejandro Luna F.
Partner OLVARES
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Patent Term Compensation for the Life Sciences

Patent term compensation is a legal procedure whose nature and purpose is to adjust the reduction in the effective enforcement of the exclusive rights of the patented invention, which mainly occurs due to delays in the process of granting the patent by the competent authority. As for Mexico, this authority lies with the Mexican Institute of Industrial Property (IMPI). The procedure of a patent term compensation is already included in the Federal Law for the Protection of Industrial Property, as well as in other international legal instruments.

The current Mexican patent law Article 53 establishes as a rule that patents are valid for 20 years, without the possibility of extension. It is, therefore, a temporary right with a limitation of 20 years. However, according to the LFPPI Article 126, one can obtain a compensation certificate for unjustified delays in granting the patent. Articles 126 and 127 states as follows:

Article 126.- When there are unreasonable delays in the processing of a patent, directly attributable to the Institute, which results in a period of more than five years between the date of the filing of the application in Mexico and of the granting of the patent, a supplementary certificate may be granted to adjust its validity, upon request of the interested party.

Article 127.- The validity of the complementary certificate referred to in the previous article may not exceed five years.

Although the Mexican Patent Office in Mexico (IMPI) has conducted considerable and plausible efforts to diminish the backlog in patent prosecution proceedings, patent validity compensation is a practical and welcome legal procedure in our legal system. Especially since it has a preventive effect by urging the authorities not to cause delays in the granting of patents and, if delays should happen, compensates for the resulting delays to the owner for not obtaining the exclusive rights on time.

However, the procedure consists of very specific limitations and conditions. Firstly, to obtain the complementary certificate, one must be able to prove that there has been at least five years between the filing of the application in Mexico and the granting of the patent. Furthermore, this delay must both be deemed unreasonable and be directly attributable to the Authority. Once a request has been made, the IMPI assesses and determines its approval and issues a resolution. The final compensation is determined on a case-by-case basis.

In addition to domestic regulation, various international treaties operating with the patent compensation procedure have been signed and ratified by Mexico, such as the Treaty between Mexico, the United States and

Canada (USMCA),^[1] the Trans-Pacific Partnership Treat (TIPAT),^[2] and the “Free Trade Agreement between Mexico and the European Union (TLEECUEM).^[3] The procedure becomes effective when there has been an inexcusable delay by a granting authority and when it has been established that the delay has surpassed the limit of five years. This is both in harmony with domestic legislation and in accordance with Article 1 and 133 of the Constitution.

The above-mentioned legal instruments are the only regulations in force that control the procedure of patent validity compensation in our country. They set out the requirements and conditions for obtaining them, such as the requirement of an unjustified delay of five years from when the application was presented in Mexico. Hence, these legal instruments are the only legal possibilities to request and obtain compensation for an unjustified validity delay, which means that the delay (five years from the request in Mexico) is the originating cause for requesting the compensation, whether it began before or after the entry in force of the new law.

The compensation of patents is not limited to the field of life sciences but due to the complexity of the technology in this industry, especially in the biotechnology sector, the prosecution of patents related to this technology is often delayed in the substantive examination during the patent prosecution.

In addition, on Oct. 14, 2020, the Mexican Supreme Court issued an important precedent in a divided decision of three to two Justices, which opened the opportunity to compensate the life-term patents before the entrance of the new law, due to unjustified delays during patent prosecution. OLIVARES did not handle the case; however, there was a public version of the decision due to the issues of unconstitutionality of the Industrial Property Law (IPL). The relevant rationale in the decision is as follows:

- Because in the previous IPL there were no maximum terms for the Mexican Patent Office (IMPI) for the issuance of official actions and decisions during the patent prosecution, the effective 20 years of exclusivity is not fulfilled in all cases, since it will depend on the discretionary time that it takes the authority to carry out the formal and substantive examinations.
- Although there are some rules for the maximum response times for the procedures presented before IMPI, they are provided in administrative decrees but not in the IPL, which is not congruent with the principle of hierarchy of the law.

In short, the Supreme Court concluded that it would be suitable to compensate the life terms of the specific patent subject matter of that particular litigation, which was granted under the run out of NAFTA and the IP Law already abrogated but applied to patents prosecuted and granted before Nov. 5, 2020.

The Supreme Court ordered the Mexican Patent Office (IMPI) to issue an official communication and establish the term of validity of the specific patent in that case, according to the 17 years from the granting date, as established by NAFTA.

According to the applicable rules for these types of Supreme Court decisions, the ruling applies and benefits the complaining party only. The decision is not binding to IMPI; therefore, it is expected that IMPI will not adopt

the criteria to compensate life term patents in similar cases without a court order. For the Mexican courts, the precedent is not binding either.

The practical impact of this precedent should be analyzed in similar cases, taking into consideration the following: the unjustified delay in the particular case granted under NAFTA. The international standard included in some international treaties is five years, which was recognized in the current LFPPI in force in Mexico. In conclusion, this isolated precedent would not apply for patents that were not delayed in, in addition to other considerations contained in the precedent and that should be taken into consideration considering the specifics of each case.

After Nov. 5, 2020, patents filed and prosecuted will be compensated for delays according to the new IP Law, including the conditions and remedies. For patents prosecuted and granted before, the Supreme Court criteria would be tested on a case-by-case basis.

Minimal impacts from this precedent are expected in the coming regulation of the new IP Law, and in the event of a conflict between the USMCA and the compensation system, a completely new analysis by the Mexican courts is expected to be required, because this court decision, as mentioned, was based on the derogated IP Law and the expired NAFTA.

It is important to mention, however, that there is another procedure to compensate for the delay of the validity of a patent in the regulatory process of a patented product, such as a drug or an agrochemical, since they require authorization in the regulatory aspect of safety and efficacy before a regulatory authority. If this authorization is unjustifiably delayed, resulting in the delay of obtaining the exclusivity rights conferred by the patent, the patent validity compensation comes into effect. However, Mexico has not adopted this procedure in its domestic regulation. Furthermore, international treaties grant the Mexican authorities a transition period of 4.5 years to not only implement the procedure in its own system but to ensure that the process can be carried out. However, it is to be noted that the transition period still is in effect.

Conclusively, both procedures, both the compensation for the regulatory and for the patent delay, are not accumulative. In the countries where the procedures are implemented, the strict and specific rules for their correct application prevents abuses and unjustified requests for compensation.

[1] Article 20.44: Adjustment of the Patent Duration for Unreasonable Delays of the Granting Authority

1. Each Party shall use its best efforts to process patent applications in an efficient and timely manner, in order to avoid unreasonable or unnecessary delays.
2. A Party may provide procedures for patent applicants to request expedited examination of their patent applications.
3. If there are unreasonable delays in the granting of a patent by a Party, that Party shall provide the means so that, at the request of the owner of the patent, the term of the patent is adjusted to compensate for such delays.
4. For the purposes of this Article, an unreasonable delay includes, at least, a delay in the granting of a patent of more than five years from the filing date of the application in the territory of the Party, or from three years from the application for examination, whichever occurs later. A Party may exclude from the determination of such

delays, periods of time that do not occur during the processing or examination of the patent application by the granting authority; periods of time that are not directly attributable to the granting authority; as well as the periods that are attributable to the patent applicant.

[2] 1. Each Party shall use its best efforts to process patent applications in an efficient and timely manner, in order to avoid unreasonable or unnecessary delays.

2. A Party may provide procedures for patent applicants to request expedited examination of their patent applications.

3. If there are unreasonable delays in the granting of patents by a Party, that Party shall provide the means so that, at the request of the patent owner, the term of the patent is adjusted to compensate for such delays.

4. For the purposes of this Article, an unreasonable delay includes, at least, a delay in the granting of a patent of more than five years from the filing date of the application in the territory of the Party, or from three years from the application for examination, whichever occurs later. A Party may exclude from the determination of such delays, periods of time that do not occur during the processing or examination of the patent application by the granting authority; periods of time that are directly attributable to the granting authority; as well as the periods that are attributable to the patent applicant

[3] Text in Spanish not available, however, article 25.46 contains the obligation to grant compensation for delays greater than 5 years.