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Pharmaceutical IP and competition law in Mexico: overview

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PATENTS

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Patent applications are regulated by the Federal Law for the Protection of Industrial Property (IP Law) and its regulations. The new IP Law came into force on 5 November 2020.

Patentable inventions must:

- Be novel.
- Result from an inventive step.
- Be industrially applicable.

Scope of protection

The following subject matter is not patentable in Mexico:

- Inventions whose commercial exploitation is contrary to public order or contravenes any legal provision, including those whose exploitation must be prevented to protect the health or life of people, animals or plants, or to avoid serious damage to the environment. These include:
  - cloning procedures for human beings and their products;
  - procedures for modifying the germinal genetic identity of human beings and their products, when they imply the possibility of creating a human being;
  - uses of human embryos for industrial or commercial purposes; and
  - procedures for modifying the genetic identity of animals which cause suffering without substantial medical or veterinary utility for man or animal.
- Plant varieties and animal breeds, except micro-organisms.
- Essentially biological processes for obtaining plants or animals, and the products resulting from these processes.

The following are not considered inventions in Mexico:

- Discoveries, scientific theories and principles.
- Mathematical methods.
- Literary, artistic works and other aesthetic creations.
- Schemes, plans, rules and methods for the exercise of intellectual activities, games, commercial activities, or the conduct of business.
- Computer programs.
- Presentations of information.
- Biological and genetic material, as found in nature.
- Medical procedures and therapeutic methods (although a patent can be obtained for a therapeutic method by drafting the claims in a Swiss-style format, that is, claiming the medical use of the compound for the treatment of a specified illness).
- Juxtapositions of known inventions or combinations of known products, or alterations of the use, form, dimensions or materials of such inventions or products, except where they are so combined or merged that they cannot function separately or where their particular qualities or functions have been so modified as to produce an industrial result or use that is not obvious to a person skilled in the art.

Products and processes can be the subject of patent protection under the IP Law. The Mexican Patent and Trademark Office (*Instituto Mexicano de la Propiedad Industrial*) (IMPI) grants patents protecting compounds, formulations, uses and manufacturing processes for medicines.

New uses of pharmaceutical or biotechnological compounds or compositions have been patentable for a long time in Mexico. However, the new IP Law provides that new uses are only patentable if they are not obvious to a person skilled in the art.

Regulations of the new IP Law are still pending. It is expected that they will recognise the patentability of first, second and further medical uses, since purpose-limited product and Swiss-type claims are accepted in practice to claim new uses.

2. How is a patent obtained?

Application and guidance

Applications must be filed with the IMPI. Details on the application procedure and government fees are available in Spanish only on the IMPI's website (*www.impi.gob.mx*).

Process and timing

Generally, it takes four to six years to obtain a patent in Mexico, depending on the field of technology.

A patent application contains a statement that must include:

- A description of the invention that is sufficiently clear and complete to allow it to be fully understood, and to guide any person knowledgeable in the field.
- The best method known by the applicant for putting the invention into practice.
- Drawings required to understand the description, when necessary.
- A claims chapter, which must be clear and concise, and must describe the concept of the invention without overlapping with the description.

If the application is filed in English, a Spanish translation must be filed within two months from the filing date.

For applications under the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention), a certified copy of the priority right document must be filed within three months from the filing date.

The IMPI conducts a formal examination of the documents and can order clarifications or further details, or that an omission be remedied. The IMPI will usually issue an official communication to request any outstanding documents four to six months after filing. The applicant has two months (plus two additional months on payment of extra fees) to comply with a request. If the applicant fails to comply, the application is deemed abandoned.

After all the formal documents have been filed, the IMPI issues an official communication that covers any priority claimed, when applicable. An abstract of the application is published in the *Official Gazette* 18 months after filing of the priority claim, or if no priority is claimed, 18 months from the filing date.

Examination on the merits of the invention starts automatically after the corresponding fees are paid on filing of the application.

An official decision on the application is issued about three years after the filing date, either requesting amendments to the claims (for example, clarification regarding novelty), or granting the protection sought and requesting payment of the final IMPI fees, together with payment of the first five annual fees.

The IMPI has implemented Patent Prosecution Highway (PPH) pilot programmes to recognise examinations by the:

- United States Patent and Trademark Office (USPTO).
- Japanese Patent Office (JPO).
- Spanish Patent and Trademark Office.
- Korean Intellectual Property Office.
- State Intellectual Property Office of China.

These programmes are an attempt to accelerate pending applications.

On 7 December 2020, the USPTO and IMPI announced the launch of a parallel patent grant (PPG) initiative. This allows for patents to be granted in Mexico based on published US patents. The aim is to expedite the examination of Mexican applications for which there is a corresponding US patent, and therefore reduce application processing times (currently three to five years from filing to grant).

While an applicant must request to benefit from the PPH before the issuance of a first office action, the IMPI will directly invite applicants to participate in the PPG. If the applicant agrees, they must pledge to claim the same matter that is covered by the corresponding US patent. However, the Director of the IMPI has stated that applicants will still be able to request participation in the PPG programme. The specific procedures for requesting/inviting participation in the programme are yet to be determined.

Within two months following publication of the patent application, third parties can file information related to the patentability of the invention with the IMPI. This does not suspend the application process and the IMPI has discretion whether to consider the information filed. The third party is not considered a party to the patent prosecution and does not have access to the patent file or immediate legal standing to challenge a granted patent. After a patent is granted, anyone can inform the IMPI of causes of invalidity. The IMPI can consider such information to initiate *ex officio* cancellation proceedings.

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

The term of a Mexican patent is 20 years from the filing date of the patent application in Mexico. For Patent Cooperation Treaty 1970 (PCT) applications, the effective filing date is the date of filing of the international patent application.

Extending protection

The new IP Law allows patent owners to request an extension of their patent term to compensate for delays during prosecution. This only applies to patents that are filed and granted after 5 November 2020.

Under the new system, a complementary certificate can be granted when both:

- There are unreasonable delays directly attributable to the IMPI.
- The patent was granted more than five years after the application filing date of in Mexico.

The validity of a complementary certificate cannot exceed five years. The IMPI will determine the period that corresponds to an unreasonable delay (based on one day for every two days of unreasonable delay). A complementary certificate will take effect the day after the expiration of the original 20-year patent term and will confer the same rights as the patent from which it derives.

On 14 October 2020, the Mexican Supreme Court issued an important decision that opens the opportunity to extend the term of patents due to unjustified delays during patent prosecution under the old IP law. The Supreme Court held that the effective 20-year protection period is not ensured in all cases, as the IMPI is not subject to statutory time frames during patent prosecution. However, this ruling is only applicable to the parties to the case and not binding on the IMPI. Therefore, it is expected that IMPI will not extend the term of patents in similar cases without a court order. The decision is not binding on Mexican courts, but is highly persuasive.

The United States-Mexico-Canada Agreement (USMCA) provides for the extension of patent protection in cases of unreasonable curtailment of the effective patent term as a result of the time taken to obtain marketing approval. However, this mechanism has not been implemented into national law.

4. How can a patent be revoked?

The validity of a patent can be challenged through a nullity action before the IMPI.

Under the previous IP Law, a patent can be declared invalid by proving one of the following (these apply to patents granted before 5 November 2020):

- The patent covers subject matter that cannot be regarded as an invention, product or process.
- The subject matter qualifies as an invention but the patent does not meet one or more of the patentability requirements (that is, novelty, inventive activity or step and industrial application).
- The patent was granted in contravention of the law and does not comply with formal or technical legal provisions.
- The patent was granted due to an error or serious oversight, or was granted to someone not entitled to obtain it.

A nullity action based on the first three grounds can be brought at any time. A nullity action based on the fourth ground must be

brought within five years from the date of publication of the patent in the *Official Gazette* or when registration becomes effective.

The new IP Law provides for the following invalidity grounds (these apply to patents granted after 5 November 2020):

- The patent covers subject matter that cannot be regarded as an invention.
- Lack of novelty, inventive activity or step and industrial application.
- The patent specification does not sufficiently disclose the invention.
- Lack of support in the application as filed.
- Divisional applications granted in violation of the IP Law.
- The protection conferred by the patent has been extended by an amendment that should not have been allowed.
- Mistakes in the recognition of priority rights that affect the novelty or inventive step of the invention.
- Double patenting.
- The patent was granted to a person who was not entitled to the patent.

Nullity actions based on all of the above grounds can be brought at any time.

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

The IP Law grants patentees the right to the exclusive exploitation of the patented invention and to exclude others from making, using, offering for sale or importing the protected invention. In a patent infringement action, the claimant must prove either of the following:

- Unauthorised production, offer for sale or import of the patented invention. If a claimant claims infringement of a patented process, the defendant must prove use of a process other than the patented process.
- Unauthorised use of the patented invention. The claimant must prove that the patent claim or claims cover the alleged infringing product or process. The Mexican IP Law only recognises literal infringement, meaning that the infringing product or process must fall within the literal scope of the claim(s). There is no doctrine of equivalence. The scope of the claims is determined by their wording, aided by the description and drawings.

The IP Law does not recognise a contributory infringement doctrine.

In November 2016, the First Circuit Court issued a non-binding isolated opinion that opened the door to the application of the doctrine of equivalents. The court concluded that peripheral interpretation, based on identity or equivalence, constitutes a method for establishing infringement.

Claim and remedies

Proving patent infringement in Mexico is difficult, as Mexico has a strict civil law system with formalistic rules for both evidence and the conduct of proceedings.

Infringement actions must be filed with the IMPI. After admitting the action, the IMPI serves a notice of the action on the alleged infringer, who has ten working days to reply.

On request, the IMPI can order provisional injunctions before the filing of an infringement claim or during proceedings. The right holder must file an administrative infringement action within 20 days after an injunction order.

Both the claimant and the alleged infringer must submit evidence at the time of filing or responding to the claim. Subsequently, the IMPI sets a deadline for the parties to file closing allegations.

The IMPI's decision can be appealed either to the:

- IMPI, through a review recourse. A recourse must be filed within 15 working days from notification of the IMPI's decision.
- Specialised IP Chamber of the Federal Court for Administrative Affairs (FCA). An appeal must be filed within 30 working days from notification of the FCA's decision.

The parties can then appeal the FCA's decision before a federal circuit court within 15 working days from notification of the decision.

The IMPI can impose certain preliminary measures while investigating the infringement, for example it can:

- Recall or prohibit the circulation of infringing goods.
- Withdraw infringing articles from circulation, including tools used in the manufacture, production or obtaining of infringing articles.
- Order the alleged infringer or third parties to suspend or cease all illegal acts.
- Suspend the provision of services or close an establishment, when other measures are insufficient to prevent or avoid a violation of rights protected by law.

Under the old IP Law, an applicant only had to allege a violation of their IP right and post a bond to obtain a preliminary injunction. To obtain the lifting of an injunction, the respondent only needed to post a counter-bond.

Under the new IP Law, the IMPI must decide on the implementation or lifting of preliminary injunctions by considering the:

- Strength of the claim (prima facie case).
- Evidence submitted by the parties.
- Effect of granting the injunction on the public order and the common good.

The current system requires parties to first obtain a final declaration of infringement from the IMPI before requesting compensation in the civil courts. The new IP Law offers two new options to file a claim for patent infringement:

- File a civil action directly with the civil courts. This gives the civil courts the authority to resolve disputes in accordance with the IP Law. However, if the validity of the IP right is challenged, the civil procedure will be suspended until the IMPI decides on the invalidity action.
- File an infringement action with the IMPI and request the determination of damages in a special incidental proceeding, once the infringement is declared. The decision on damages can then be enforced by the civil courts. However, according to the transitory provisions of the new law, this option will only be available when the IMPI is ready to implement it. There are currently no clear indications of when this may occur.

Dispute resolution and settlement

The new IP Law formally introduced conciliation as an alternative dispute resolution mechanism in infringement proceedings. It is unclear whether the conciliation procedure will also apply to isolated cancellation actions and cancellation actions filed as counterclaims.

The conciliation process involves the following steps:

- Conciliation can be requested in writing by any of the parties and at any time before a decision is issued. The conciliation does not suspend the contentious proceedings.
- The interested party files a conciliation proposal, which must be served on the opposing party within five business days.
- The party receiving the proposal can accept the proposal, refuse to negotiate or file a counterproposal. If no response is submitted, the conciliation proposal will be presumed to have been rejected, putting an end to the conciliation procedure.
- If the proposal for conciliation is accepted, the IMPI will require the parties to file a duly formalised agreement.
- If there is a counterproposal, the parties will be summoned to up to two negotiation meetings, in which the IMPI will try to mediate between the parties. A party that does not attend negotiation meetings without valid reasons can be subject to a financial penalty. If neither party attends, the negotiation will be presumed to have be rejected.
- If preliminary injunctions were imposed during the infringement proceedings, the parties must agree on the destination of bond posted and/or seized goods.
- The agreement reached by the parties must not be contrary to public order, public health or the general interest of society. It is final and binding on the parties.

Generally, the execution of private settlement agreements is kept confidential.

Relevant international patent instruments and processes

The following international instruments apply in Mexico:

- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- Strasbourg Agreement Concerning the International Patent Classification 1971.
- PCT.
- Paris Convention.
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.

6. Are there non-patent barriers to competition that protect an originator's monopoly over an authorised medicinal product?

Mexican law is silent about data package exclusivity (DPE). Based on TRIPS and the North America Free Trade Agreement (NAFTA), and the superiority of international treaties over domestic law, certain court decisions have recognised and ordered the Federal Commission for Protection against Sanitary Risks (COFEPRIS) to observe DPE.

On 19 June 2012, COFEPRIS published an internal decree on its website, providing guidelines to observe and protect DPE in Mexico. According to the guidelines (and minimum requirements under NAFTA), a marketing authorisation holder benefits from a five-year exclusivity period during which their information cannot benefit or be used to support a third party application for registration of a generic drug.

These guidelines show that COFEPRIS has been willing to recognise and protect DPE by reference to NAFTA and TRIPS. The decree provides a higher degree of certainty for innovators. However, certain issues require further clarification, for example whether:

- The guidelines apply to biological products.
- Other key approvals, such as new formulations and indications, are protected.
- The proceedings and measures to enforce and observe DPE rights, which are not covered by the decree.

The main issue is the legal force of the decree in view of the lack of domestic law recognising DPE.

The United States-Mexico-Canada Agreement (USMCA), which replaced NAFTA, entered into force on 1 July 2020. This treaty will have an impact on DPE in Mexico. However, the current text of the USMCA only recognises a five-year DPE for new chemical molecules. The provisions on new formulations or combinations and biologics were removed by amendments to the agreement, which will lead to issues to obtain DPE in Mexico for these products.

Additionally, the Mexico-EU Trade Agreement requires at least six years of DPE for both small molecules and biologics, although the agreement has not yet fully entered into force.

DPE is not automatically conferred on approval; a petition must be filed with COFEPRIS and in many cases it is necessary to start proceedings to obtain a court decision ordering DPE.

7. Are any restrictions placed on licensing or transferring patents to foreign parties? Are intellectual property transfers for inventions funded, or partially funded, by public investment restricted?

There are no such restrictions.

TRADE MARKS

8. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Legislation and scope of protection

The IP Law and its Regulation regulate trade marks in Mexico.

A trade mark is any sign that:

- Is perceptible by the senses and capable of being represented in a way that allows to determine the clear and precise object of protection.
- Distinguishes products or services from others of the same type or class in the market.

The IP Law expressly provides that trade mark protection is also available for:

- Non-visible signs, such as smell marks and sound marks.
- Certain animated marks, such as holograms.
- Trade dress.

All traditional and non-traditional trade marks (scent, sound marks, holograms, and so on), as well as trade dress, can be protected if they are sufficiently distinctive and can distinguish the goods or services to which they apply from others of the same class (*Article 172, IP Law*).

General conditions and specific rules for naming medicines

General conditions. The following cannot be protected as trade marks:

- Marks that are identical or confusingly similar to previously registered marks (or marks for which registration is pending) and applied to identical or similar products or services. However, consent and coexistence agreements can be used to overcome this ground for refusal of registration.
- Descriptive and generic marks (although acquired distinctiveness is recognised).
- Geographic indications and names of places that are characterised by the manufacture of certain products.
- Three-dimensional forms of common usage or imposed by their nature or industrial function.

(*Article 173, IP Law.*)

Brands for medicinal products can be registered as trade marks.

Specific rules for naming medicines. Manufacturers must obtain a marketing authorisation to sell medicines and certain medical devices. To apply for a marketing authorisation, the distinctive name of the medicine must be pre-approved by COFEPRIS (*Article 2, Section IV, Health Supplies Regulation*).

The following main rules apply to distinctive names for medicines:

- "Distinctive name" means the name or trade mark assigned to a pharmaceutical product to distinguish it from other similar products (*Article 2, Section IV, Health Supplies Regulations*).
- Medicines must be identified by their distinctive and generic names for use and marketing purposes (*Article 225, Health Law*).
- A distinctive name must not:
  - refer to the composition of the product or its therapeutic action; or
  - relate to diseases, syndromes, symptoms, anatomical data or physiological phenomena, except for vaccines and biological products (*Article 225, Health Law*).
- A proposed distinctive name must not be identical or similar to the name of another approved medicine. Under the "three-letter rule", there must be a difference of at least three letters in each word of the proposed name and a previous name to prove dissimilarity (*Article 23, Health Supplies Regulations*).
- A distinctive name can be used for pharmaceutical products that have the same active ingredient and have been approved by the same laboratory, but have different pharmaceutical forms or doses (*Article 23, Health Supplies Regulation*).

There is no regulation regarding conflicts between registered trade marks and marketing authorisations or distinctive names.

The IMPI usually consider the three-letter rule when analysing the similarity of pharmaceutical trade marks, although the rule is not binding on them. However, the Health Supplies Regulation does not require COFEPRIS to consider senior trade mark registrations (for pharmaceutical products) when examining the similarity of distinctive names. This inconsistency has had unfortunate consequences, including contradictory decisions by the IMPI and COFEPRIS regarding the likelihood of confusion of trade marks and distinctive names.

Further, the IMPI and COFEPRIS have different databases. The IMPI's database comprises all trade mark applications and registrations that have been filed with the agency or its predecessors, while COFEPRIS' database only contains distinctive names approved for medicinal products, regardless of whether they are in use.

COFEPRIS' system enables pharmaceutical companies to obtain a pre-approval certificate for distinctive names, which is valid for 90 days. However, the system only allows ten certificates per company and the certificates do not bind COFEPRIS, which can still refuse marketing authorisation for a pre-approved distinctive name. A refusal can be challenged before the federal courts.

The inclusion of international non-proprietary names (INNs) or INN stems as part of pharmaceutical trade marks creates conflicting situations.

The Health Law (*Article 225*) expressly prohibits the use of pharmaceutical trade marks that clearly resemble INNs, and the IP Law (*Article 173*) prohibits registration of generic names. Accordingly, the IMPI has no legal basis to refuse a trade mark that comprises a stem or an INN as well as an additional distinctive elements that make the trade mark registrable as a whole.

The IMPI therefore faces a challenge in following the World Health Organization's recommendations to safeguard the proper use of INNs and to avoid the registration of trade marks derived from INNs.

9. How is a trade mark registered?

Application and guidance

Applications must be submitted to the IMPI. Details on the application procedure and government fees are available in Spanish only on the IMPI's website (*www.impi.gob.mx*).

Process and timing

A trade mark application must include the following information:

- The applicant's full name and address.
- A representation of the trade mark (graphic elements that are not part of the mark must be indicated by dashed or dotted lines).
- A description of the goods or services covered.
- Information on use in commerce in Mexico. Non-use applications are allowed, as use in commerce is not a requirement to obtain registration in Mexico. However, if the trade mark is already in use in Mexico, it is recommended to provide the full date of first use of the mark (day, month and year). This information will enable the applicant to have priority rights over other applicants who intend to challenge the registration based on use of a similar mark covering similar goods or services.
- The applicant's factory address, business address or commercial establishment (if the mark is in use in Mexico).
- Convention priority (where applicable). If convention priority is claimed, the applicant must indicate the jurisdiction of the priority application, application number, date of filing, and exact description of the goods and services covered.

A trade mark application involves the following process:

- A formal examination, which checks compliance with the formal legal requirements (for example, the official application form must be duly completed and the government fees paid). If any formal information or documents are missing, or if the products/services are not correctly classified, the IMPI will give the applicant two months to remedy the defect(s) (this period can be automatically extended for a further two months).
- A second examination of the registrability of the mark (without evidence of use), that is, whether it complies with the legal

conditions for registration. The examiner will consider both relative grounds for refusal (prior rights) and absolute grounds for refusal (inherent registrability of the mark). If there are any objections on registrability, the IMPI will give the applicant two months to remedy the defect(s) (this period can be automatically extended for a further two months).

It generally takes four to seven months for the IMPI to conduct both examinations.

Filed applications are published for opposition in the *Industrial Property Gazette* within ten working days. If an opposition is filed, the applicant must file a response within four months of service of the opposition. If no response is filed, the registration application will be considered as abandoned. The party that filed the opposition cannot later file an invalidity action against the registered trade mark on the same grounds and based on the same evidence. This is probably the most significant drawback of the current opposition system.

The deadline to file final arguments in opposition proceedings is now five days from notification by the IMPI. If the application filing date changes during the prosecution of a trade mark application for any reason, the application will be published again for opposition purposes.

If there are no requests for further information, oppositions and/or objections to registration, the average cost for obtaining a Mexican non-priority trade mark registration is about USD800.

10. How long does trade mark protection typically last?

Trade mark registration lasts ten years from either the:

- Date of grant, for trade marks filed on or after 5 November 2020.
- Filing date, for trade marks filed before 5 November 2020.

Protection can be renewed indefinitely for further ten-year periods.

Renewal applications must be filed along with a declaration of use (DOU) in which the registration holder declares under oath that the trade mark is actually in use in Mexico. If no DOU is filed, the IMPI will give the registration holder two months to file a DOU.

The filing of a DOU is not mandatory when the renewal application is filed by a lien holder recorded with the IMPI.

Renewal of trade mark registration can be requested from six months before its renewal date. However, the IMPI will accept and process renewal petitions filed within a six-month grace period after the renewal date, on payment of an additional government fee.

11. How can a trade mark be revoked?

Non-use and generic use

A trade mark registration can be subject to cancellation for non-use when either:

- The trade mark is not used for three consecutive years in relation to the goods or services for which it is registered.
- The DOU (*see Question 10*) is not made in accordance with Article 235 of the IP Law.

This does not apply when either:

- A duly licensed holder or user has used the mark for three consecutive years immediately before the filing date of the cancellation action.
- There are legitimate reasons for non-use that are beyond the control of the trade mark owner (for example, import restrictions or other government requirements).

The new IP Law has introduced the possibility to bring partial non-use cancellation actions. Therefore, the IMPI can cancel a registration either in its entirety or in connection with specific products or services for which the trade mark is not used. Under the previous law, registration could be maintained entirely if the use of the trade mark was proved in connection with any of the products or services covered.

A trade mark registration can also be cancelled if it has become generic as a result of the owner's inactivity or acts.

Invalidity

Under the new IP Law, a trade mark can be declared invalid on any of the following grounds:

- Registration was granted in violation of the IP Law or any other law that was in force at the time of registration.
- The trade mark is identical or confusingly similar to another mark that has been used continuously in Mexico or abroad in relation to the same or similar products or services before the application filing date.
- The registration holder does not provide evidence of the date of first use stated in the application.
- There is an earlier identical or similar registered trade mark covering identical or similar goods or services.
- The registration was obtained in the name of an agent, representative, user or distributor without the owner's authorisation.
- The registration was obtained in bad faith (for example, to obtain an unfair benefit or advantage and undermine the legitimate interests of a third party).

The IMPI can partially invalidate a trade mark based on a prior trade mark registration. If the IMPI issues a ruling declaring the partial invalidity of a trade mark registration, a record will be included in the registration certificate stating the modifications and the reasons for them. Partial invalidity can only be declared in connection with the products or services covered by the trade mark registration, not the elements constituting the mark.

Invalidity actions will not be admitted if they are based on the same arguments and evidence submitted in opposition proceedings already resolved by the IMPI (*see Question 9*). This new rule introduced by the IP Law may have a negative impact on the IP system. In cases in which an opposition was filed but was unsuccessful, it will not be possible to further try to invalidate a registration using the same arguments and evidence, making it impossible to review the IMPI's decision and defeating the purpose of the invalidity grounds specifically designed to cancel registrations granted by error, inadvertence or wrong interpretation.

A declaration of invalidity has retroactive effect.

12. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

In an administrative infringement action, the claimant must prove that the defendant used a confusingly similar/identical trade mark without authorisation in relation to identical or similar goods or services to those covered by the registration.

Criminal proceedings can be brought against counterfeit goods that bear an identical trade mark to that of the claimant (counterfeiting).

A claimant can also bring an action for unfair competition. In this case, the claimant must prove that use of the trade mark by the defendant makes some form of false representation that may lead consumers to believe that the defendant's goods or services come from the claimant.

Claim and remedies

The same applies as for patent infringement (*see Question 5, Claim and remedies*).

Dispute resolution and settlement

See *Question 5, Dispute resolution and settlement.*

Relevant international trade mark instruments and processes

The following relevant international instruments apply in Mexico:

- TRIPS.
- Paris Convention.
- Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol).
- Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.

13. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

COFEPRIS has statutory authority to:

- Seize any drug held for sale that is adulterated, misbranded, mislabelled and/or has expired.
- Inspect at reasonable times, subject to reasonable limits and in a reasonable manner any place where health products are manufactured, packed and/or held for marketing.

Right holders can enforce border measures and the remedies provided by the IP Law, if applicable.

Measures against counterfeit medicines have been introduced, including customs protection. Customs and the IMPI have created a trade mark enforcement database that contains details of registered trade marks of owners wishing to monitor their rights at the 49 customs checkpoints at the country's borders, ports, bus and train stations, and airports. Customs and the IMPI are currently analysing whether the customs database of registered trade marks could be extended to patents.

Regarding medicines, pharmaceutical substances, chemicals and active pharmaceutical ingredients (APIs), Customs' efforts are limited to detecting prohibited drugs and narcotics. Customs can collaborate with rights holders to detect and seize APIs based on IMPI-ordered border measures. Thanks to the co-operation between Customs and the IMPI, bulk border seizures of patented APIs have taken place.

IP AND COMPETITION LAW ISSUES

14. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

The Federal Economic Competition Commission (*Comisión Federal de Competencia Económica*) (COFECE) (*www.cofece.mx*) enforces the competition legal framework in Mexico. This regulatory authority is an administrative agency with technical and operational autonomy, which is not supervised by but related to the Ministry of Economy.

The main legislation is the:

- Economic Competition Federal Law (*Ley Federal de Competencia Económica*) (ECL).
- ECL Regulations (*Reglamento de la Ley Federal de Competencia Económica*).
- Administrative Rules (*Disposiciones administrativas de carácter general reglamentarias*).

The COFECE has statutory authority to review practices by pharmaceutical companies. In 2010, the COFECE imposed a fine on six pharmaceutical companies for anti-competitive practices in public tender proceedings organised by the Social Security Institute (*Instituto Mexicano del Seguro Social*) (IMSS). The COFECE is currently conducting an investigation into alleged irregularities in the market for the production, distribution and marketing of medicines.

15. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products? What compliance issues do parties to pharmaceutical technology licences and pharmaceutical distribution agreements need to consider?

Restrictive agreements and abuse of patent rights

An action can be brought before the COFECE against activities falling outside the scope of a patent, such as:

- Non-compete agreements for products that are not covered by the patent claims.
- Product tying.
- Unfair competition (for example, advertising that a product is better than an alternative for the sole reason of it being covered by a patent).

Actions can also be brought before the COFECE for other forms of abuse of patent rights, such as clearly unfounded attempts to enforce a patent.

Compulsory licensing

After three years from the date of grant of the patent or four years from the filing date, whichever is later, any person can request from the IMPI the grant of a compulsory licence when a patent has not been used in Mexico, except if there are justified reasons for non-use.

A compulsory licence will not be granted when either:

- The patent holder or a licensee has been importing the patented product or the product obtained by the patented process.

- A licensee has worked the patent, provided that the licence is recorded with the IMPI.

A party applying for a compulsory licence must have the technical and economic capacity to efficiently work the patented invention.

Before the grant of the first compulsory licence, the IMPI will provide the patentee with the opportunity to begin working the patent within one year from the date notification. If the patentee does not work the patent within that time frame, the IMPI will decide on the grant of a compulsory licence following a hearing with the parties. If the IMPI decides to grant a compulsory licence, it will set out its duration, conditions, field of application and amount of royalties to be paid to the patent holder. The royalties are determined by the IMPI after a hearing with the parties. Royalties must be fair and reasonable.

The authors are not aware of any compulsory licences being granted in recent years.

16. Are there competition issues associated with the entry of generic pharmaceuticals in your jurisdiction?

Generics must have a marketing authorisation to be sold and imported into Mexico.

There is a linkage system between COFEPRIS and the IMPI, which aims to prevent the granting of marketing authorisations in violation of patent rights. Under the IP Regulations, the IMPI must publish every six months a gazette that includes patents covering allopathic medicines (*Linkage Gazette*). The initial IMPI position was that only patents relating to a compound were relevant to linkage review (excluding formulation and use patents). On 31 July 2012, for the first time the IMPI included formulation patents in the *Linkage Gazette*, in accordance with a 2010 ruling of the Mexican Supreme Court (*Jurisprudence No. 2a./J.7/2010, Federal Judicial Gazette, No. XXXI, page 135*).

Use patents are only included in the *Linkage Gazette* by court orders, since the IMPI consider that they should not be included in the linkage system.

Under the linkage regulations, on the filing of the application, the applicant must either:

- Prove that it is the owner or licensee of the patent over the active ingredient of the product (recorded with the IMPI).
- State under oath that their application does not violate the list of products published in the *Linkage Gazette* and complies with patent law.

If a generic application is approved while the corresponding patent is still in force, the patent holder or licensee will be entitled to bring a court action against the marketing authorisation approval and a patent infringement action against the manufacture and sale of the generic products.

Patent holders may also benefit from DPE (*see Question 6*).

Patent rights have no effects against third parties using, manufacturing, offering to sell or importing a patented product for the exclusive purpose of experimentation and obtaining information necessary for sanitary registration of a medicine (*Article 57, section II, IP Law*).

17. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

The Ministry of Public Function (SFP), which has the power to impose fine on companies for acts of corruption or bad practices, has prohibited certain drug distributors from participating in public contract tenders for allegedly monopolising purchases from Mexico's social security institutes.

18. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

In relation to trade marks, parallel imports are allowed if the product was legally introduced in the country of origin. The packaging and labelling of pharmaceuticals are governed by the Health Law and its Regulations and require approval by COFEPRIS. Altering or modifying the authorised packaging or labelling of approved pharmaceutical products may be considered a criminal offence. The IP Law does not specifically address patents in this context. However, it is likely that the principle of exhaustion of rights also applies to patents.

On January 2020, the Ministry of Health published an official administrative decree that authorises the Mexican authorities to import medicines that do not have a marketing authorisation in Mexico if this is necessary to guarantee the supply of medicines for the correct and timely provision of health services to the population.

19. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? Are there any formalities or other requirements that must be complied with to make the licence enforceable?

There is no requirement for a patent or trade mark licence and payment of royalties under it to a foreign licensor to be approved by a government or regulatory body.

Recording a patent or a trade mark licence is not mandatory and the agreement is enforceable between the parties regardless of recordal. However, to be enforceable against third parties, and to ensure the title holder can use the trade mark or patent, the licence must be recorded with the IMPI (*IP Law*).

Practical Law **Contributor profiles**

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Areas of practice. Biotechnology/pharmaceutical law; intellectual property litigation; anti-piracy; anti-counterfeiting; alternative dispute resolution; IP enforcement.

Recent transactions

- Participated in cases relating to the unconstitutionality and inefficiency of certain amendments to the Federal Law of Administrative Proceedings in Mexico, which have affected the venues for challenging resolutions of the Mexican Institute of Industrial Property (IMPI).
- Sponsor of a proposal to modify the IP litigation system, limiting the IMPI to an exclusive registration authority, transferring jurisdiction to civil courts for infringement cases, and to administrative courts for cases related to the annulment of trade mark registrations and patents.

Languages. English, Spanish

Professional associations/memberships. Former Vice-President of the Mexican Association for IP Protection (AMPPI); member of the International Trademark Association (INTA).

Publications

- *Imports shine the spotlight on experimental use defence, 2013, Intellectual Asset Management magazine issue, IP Media Group.*
- *Maximising IP rights in the life sciences industry, 2012, Intellectual Asset Management magazine issue 54, IP Media Group.*
- *New Regulations Pending, 2011 edition of Life Sciences, Mexico Chapter: Biologic Drugs, Managing Intellectual Property Magazine.*
- *Supreme Court upholds the worth of formulation patents, 2010, IAM Life Sciences 250, Formulation patents in Mexico.*
- *Pharmaceutical trademarks, World Trademark Review, Country correspondent: Mexico, October/November 2009.*

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Professional qualifications. Bachelor Degree, National Autonomous University of Mexico (UNAM), 1995

Areas of practice. Pharmaceutical law; IP litigation and enforcement.

Recent transactions

- Successfully litigated to correct the term of pharmaceutical patents granted under transitory Article 12 of the Law for the Promotion and Protection of Industrial Property.
- Obtained a declaration of infringement of patents protecting active ingredients, medical uses, pharmaceutical formulations and production processes of biotechnological drugs, to maintain market exclusivity for patent holders.
- Obtained the nullity of marketing authorisations of generic medicines for violating the Mexican linkage system on behalf of holders of patents protecting active ingredients, pharmaceutical formulations and medical uses.
- Successfully representing clients in civil actions for damages for infringements of industrial property rights.
- Acted in the action for unconstitutionality of Article 167bis of the Health Supplies Regulation, on the ground that it does not provide the right to patent holders to be heard during the prosecution of marketing authorisations.

Languages. English, Spanish

Professional associations/memberships. Mexican Association for IP Protection (AMPPI).

Publications

- *Preliminary injunctions and infringement actions, Intellectual Property and Pharmaceutical Research, January 2012.*
- *Approval of follow-on biologics in Mexico, Intellectual Asset Management, July/August 2011.*
- *Reform of preliminary injunctions, Managing Intellectual Property, October 2010.*
- *Trademark enforcement, World Trademark Review, June/July 2009.*
- *Composite trademarks, Managing Intellectual Property, January 2009.*
- *COFEPRIS ordered to cancel marketing authorisation, Managing Intellectual Property, March 2015.*

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Professional qualifications. LLM International and European Intellectual Property Law, Trinity College Dublin, Ireland, 2017; Bachelor Degree, Universidad Iberoamericana, Mexico, 2010

Areas of practice. Pharmaceutical law; IP litigation and enforcement.

Recent transactions

- Obtained the enforcement of an unpublished patent against the grant of a marketing authorisation for a generic medicine.
- Participated in the first case in Mexico leading to the revocation of a marketing authorisation of a pharmaceutical product for violation of a formulation patent listed in the *Linkage Gazette*.
- Participated in the first case in Mexico enforcing a use patent in a public tender.

Languages. English, Spanish

Professional associations/memberships. Mexican Association for IP Protection (AMPPI).

Publications

- *Damages Claims Under the New IP Law in Mexico, Mexico Business, 2020.*
- *Infringement of second medical use patents, Managing Intellectual Property, 2015.*