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Pharmaceutical IP and competition law in Mexico: overview

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PHARMACEUTICAL IP AND COMPETITION LAW IN MEXICO: OVERVIEW

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 Industrial Property Law and its regulations. Patentable inventions must (*Article 16, Industrial Property Law*):

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

Scope of protection

Products and processes can be the subject of patent protection under the Industrial Property Law. The IMPI grants patents protecting compounds, formulations, uses and manufacturing processes for medicines.

Article 19 of the Industrial Property Law excludes medical procedures from being the subject matter of an invention. However, a patent can be obtained for a therapeutic method by drafting the claims in the Swiss-style format, that is, claiming the medical use of the compound for the treatment of a specified illness.

2. How is a patent obtained?

Application and guidance

Applications must be filed with IMPI. Details of government fees are available in Spanish only at the IMPI website (*www.impi.gob.mx*).

Process and timing

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

A patent application includes a narrative statement that sets out:

- 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 invention's field.
- The best method known by the applicant of putting the invention into practice.
- Drawings required for an understanding of the description, when necessary.
- A claims chapter, which must be clear and concise, and must describe the invention's concept without overlapping with the description.

If the application is filed in English, a corresponding 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 documentation and can order clarifications or further details, or that an omission be remedied. An official communication is issued to request any outstanding documents, usually four to six months after filing. The IMPI grants the applicant a term of two months, and two additional months on payment of extra fees, to comply with these requirements. If the applicant fails to comply, the application is deemed abandoned.

After all the formal documents have been filed, an official communication is issued that notes the priority claimed, when applicable. An abstract of the application is published in the *Official Gazette*. This step normally occurs 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 begins automatically after the corresponding fees are paid with filing of the application.

An official action is issued about three years after the filing date, either requesting amendments to the claims (for example, due to disapproval or 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.

IMPI has implemented Patent Prosecution Highway (PPH) pilot programmes to accept examinations by the United States Patent and Trademark Office (USPTO), the Japanese Patent Office (JPO), the Spanish Patent and Trade mark Office (SPTO), the Korean Intellectual Property Office (KIPO) and the State Intellectual Property Office of China (SIPO). These programmes are an attempt to accelerate pending applications.

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 applications, the effective filing date is the date of filing of the international patent application.

Extending protection

There are no provisions for exclusivity term extensions or supplementary protection certificates in Mexican law.

In theory, the life term of a patent can be extended under certain international treaties (for example, the North America Free Trade Association (NAFTA)), where the health authority has delayed the process to obtain a marketing authorisation for a patented product. However, in practice no-one has yet attempted this. We would suggest that anyone seeking to extend the life term of a patent on these grounds would need to argue that the international law has supremacy over Mexico's domestic legislation. In relation to data package exclusivity, COFEPRIS has recently provided some recognition of data package exclusivity according to international treaties. In addition, Mexico is participating in the Trans-Pacific Partnership.

4. How can a patent be revoked?

The validity of a patent can be challenged through a nullity action before the IMPI. A patent can be established as invalid by proving one of the following:

- 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 standards or conditions (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.

In the first three situations the nullity action can be exercised at any time. In the fourth situation the nullity action must be exercised within five years from the date on which publication of the patent in the *Official Gazette* occurred or when registration becomes effective.

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

Conditions for infringement

The Industrial Property 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 covered invention. In a patent infringement action, the claimant must prove either of the following, without authorisation:

- Production, offering to sell or importing of the patented invention. A manufacturer can infringe directly, while infringement by sellers requires prior notice of the infringement. If a claimant claims infringement of a patented process, the defendant must prove use of a process other than the patented process. There are no grounds in the Industrial Property Law to apply the contributory infringement doctrine.
- Use of the patented invention. The Industrial Property Law only recognises literal infringement, and there is no doctrine of equivalence. The claimant must prove that the wording of the patent's claim or claims cover the alleged infringing product or process. The Industrial Property Law provides that the scope of the claims is determined by their wording, aided by the description and drawings.

The burden of proving authorised use is on the defendant. The doctrine of implied licence has not been tested before the Mexican courts.

Claim and remedies

Proving patent infringement in Mexico is difficult, since Mexico follows a strict civil law system which has formalistic rules for both evidence and proceedings. A patent infringement claim must be submitted to the IMPI. The claim is served on the alleged infringer, who then has ten working days to respond and, if applicable, bring a counterclaim. That response is then served on the claimant for the claimant to refute it. The evidence is then analysed and a decision is issued. That decision can be challenged before the federal courts. The IMPI is an administrative authority. There is no judge or jury participation in patent infringement actions.

The IMPI can take certain preliminary measures while investigating the infringement (*Article 199 bis, Industrial Property Law*). They include ordering:

- The recall of infringing goods, or preventing their circulation.
- Infringing articles to be withdrawn from circulation, including tools used in the manufacture, production or obtaining of infringing articles.
- The alleged transgressor or third parties to suspend or cease all acts that violate the law.
- Suspension of services or closure of an establishment, when other measures are insufficient to prevent or avoid a violation of rights protected by law.

Administrative infringements can incur penalties ranging from a fine up to 20,000 times the minimum wage (about US$105,000) to final closure of the establishment (*Article 214, Industrial Property Law*). Repeated infringement is also considered a criminal offence (*Article 223, Industrial Property Law*).

Once an infringement has been declared and cannot be appealed, the claimant can bring an additional civil action for damages and lost profit, accruing from the date on which the existence of the infringement can be proved (*see Article 221 bis, Industrial Property Law*). The civil courts impose a tariff scheme specifying the costs that can be claimed for reasonable attorneys' fees, regardless of whether this reflects the actual fees charged.

6. Are there non-patent barriers to competition to protect medicinal products?

Mexican domestic law is silent about data package exclusivity. However, on 19 June 2012 COFEPRIS published an internal decree on its website, providing some recognition of data package exclusivity according to international treaties. The primary features of the guidelines issued by COFEPRIS are that:

- Information submitted in a process of regulatory approval is protected against unfair commercial use and disclosure.
- Five years maximum protection. During this period of time, no one can use information provided by the innovator for the commercialisation of the drug.
- COFEPRIS will grant approvals for generics once the five years of protection lapses, unless the generic drug proves safety and efficacy independently.

Conversely, there are some pending issues, such as that COFEPRIS has stated that the guidelines do not apply to biological products. The internal decree is also silent about the proceedings and measures to enforce and observe the right, which would provide

certainty to all the involved parties. The main question and test will be the weight and strength of these guidelines as an internal decree against the lack of domestic statutory law recognising DPE.

TRADE MARKS

7. 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?

Conditions and legislation

All visible signs can be protected as a trade mark if they are sufficiently distinctive and able to identify the products or services to which they apply or are intended to apply against others in the same class (*Article 89, Industrial Property Law*).

Scope of protection

Brands for medicinal products can be registered as trade marks.

Trade marks in Mexico are regulated under the Industrial Property Law. Article 90 provides a long list of prohibitions against registration of certain signs as trade marks. In addition, Article 4 prohibits registration of marks whose content or form is contrary to public order, morals and decency, or that contravene any legal provision.

Sounds and smells cannot be protected as trade marks. Three-dimensional forms can be protected as trade marks, as they are visible signs, if they comply with the principle of distinctiveness. However, the Industrial Property Law establishes certain limitations on three-dimensional marks.

On granting marketing authorisations, COFERPRIS must ensure that when the proposed trade mark of a drug is orthographic or phonetically similar to another previously approved, this must differ at least by three letters in each word (*Article 23, RIS*). This is known as the three-letter rule.

International non-proprietary names (INNs) cannot be registered as trade marks. Article 225 of the General Health Law expressly forbids the use of pharmaceutical trade marks that clearly or even slightly resemble an INN.

8. How is a trade mark registered?

Application and guidance

Applications have to be submitted to the IMPI (*www.impi.gob.mx*).

Process and timing

An application for a new trade mark follows 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).
- A second examination of the inherent registrability of the mark (without evidence of use), that is, whether it complies with the legal conditions for registration.

The examiners then search the IMPI's database to check if there is a trade mark (on record or at the registration stage) that is similar or confusingly similar to the proposed mark. If a similar trade mark is revealed in the search, it is analysed to determine whether the confusion is triggered by graphic, phonetic or conceptual aspects, considering the similarities between the relevant products or services.

If the examiners find that a prior mark is a barrier to registration, or that the application does not comply with all the formal requirements, an official notice of this is issued, detailing these reasons and granting the applicant a two-month term (automatically extendable for a further two months) to comply or provide legal arguments. IMPI then grants or refuses the registration. On the applicant's request, the IMPI will suspend the trade mark application if legal action against prior registration begins.

If the trade mark registration for a word mark does not face any objection as to its inherent registrability, and there is no known similar or identical prior registered mark, completing registration can take three to four months. For a design trade mark, it can take at least six months because searches for prior registrations relating to designs are mostly conducted manually by the IMPI.

There is no opposition system in Mexico. The IMPI's current approach is to not recognise consent letters or co-existence agreements for identical or confusingly similar trade marks owned by different parties. The Protocol relating to the Madrid Agreement concerning the International Registration of Trademarks 1989 (Madrid Protocol) entered into full force in Mexico on 19 February 2013. However, full implementation by IMPI is still pending.

9. How long does trade mark protection typically last?

Trade mark registrations are valid for ten years from the filing date and can be renewed for any number of further ten-year periods.

Renewal of trade mark registration can be requested by the holder 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.

10. How can a trade mark be revoked?

If a trade mark is not used for three consecutive years in relation to the goods or services for which it is registered, the registration is subject to cancellation for non-use, unless either (*Articles 130 and 152(II), Industrial Property Law*):

- 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 the non-use that are beyond the control of the trade mark owner (for example, import restrictions or other government requirements).

Trade marks can also be cancelled if (*Article 151, Industrial Property Law*):

- The registration was granted in breach of the law, although the invalidity action cannot be based on a challenge to the applicant's legal representation. An action on these grounds can be made at any time.
- The trade mark is identical or confusingly similar to another that has been continuously used in Mexico or abroad before the application for registration, and is applied to the same or similar products or services. An action on these grounds must be made within three years of the trade mark's registration.
- The registration was granted on the basis of false information in the application. An action on these grounds must be initiated within five years of the trade mark's registration.

- The registration was granted by mistake. An action on these grounds must be initiated within five years of the trade mark's registration.
- The agent, representative, user or distributor of a trade mark registered abroad requests and obtains registration in his name of the trade mark or another confusingly similar one, without the express consent of the holder of the foreign trade mark. In this situation, the registration is deemed to have been obtained in bad faith. An action on these grounds can be initiated at any time.

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

Conditions

For administrative infringements, the claimant must prove use of a confusingly similar/identical trade mark by a third party without authorisation, to distinguish identical or similar goods or services to those covered by the registration.

Criminal proceedings can be brought against counterfeit goods with a trade mark identical to the one held by 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 infringer makes some form of false representation, that tends to cause consumers to believe that the defendant's goods or services come from the claimant.

Claim and remedies

Administrative actions for trade mark infringement can be brought before the IMPI. IMPI can impose a fine and order an immediate halt to the infringing activities. A civil action to claim damages in a civil court is possible once an IMPI resolution declaring infringement is final and cannot be appealed.

A criminal action against counterfeiting can be brought by filing a complaint with the attorney general's office. On receiving the complaint, the attorney general's office will conduct an inquiry, to determine whether a crime has been committed. If so, the district attorney submits the matter to a federal district judge. Criminal penalties range from between two and ten years' imprisonment, to about US$100,000 in fines. Imprisonment and fines can be imposed simultaneously.

12. 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 lapsed.
- 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 (*see Question 11*), if applicable.

The fight against counterfeit medicines in Mexico has increased in different aspects, including customs protection. Customs and IMPI are analysing whether the customs database of registered trade marks may be extended to patents.

IP and competition law issues

13. 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 Economic Competition Federal Commission (ECCF) (*www.cfc.gob.mx*) enforces the competition legal framework in Mexico. This regulatory authority is an administrative agency with technical and operational autonomy, not governed by but related to the Ministry of Economy. The primary legislation is:

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

The ECFC has statutory authority to review practices by pharmaceutical companies. In 2010, the ECFC published the imposition of a fine on six pharmaceutical companies for anti-competitive practices in public tender proceedings by IMSS. This decision is available in Spanish on the ECFC website. Apparently, this case remains under appeal.

14. Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context

Patent licensing and anti-trust law

In theory, an action could be brought against activities falling outside the scope of a patent, such as:

- Non-competition agreements for products that are not covered by the claims.
- Product-tying within that scope.
- Unfair competition activities, such as advertising that a product is better than an alternative for the sole reason of it having a patent.

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

Compulsory licensing

After three years starting 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 the patent has not been used, except if there are justified reasons for the non-use (*Article 70, IP Law*).

A compulsory licence will not be granted when the patent holder or a licensee has been importing the patented product or the product obtained by the patented process (*Article 70, IP Law*). Further, the working of a patent by a licensee will be deemed to be worked by its holder, provided that the licence has been recorded with the IMPI (*Article 69, IP Law*).

A party applying for a compulsory licence must have the technical and economical capacity to efficiently work the patented invention (*Article 71, IP Law*).

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 of personal notification given to him (*Article 72, IP Law*). Following a hearing with the parties, the IMPI will decide on the grant of a compulsory licence. If the IMPI decides to grant it, it will set out its duration, conditions, field of application and amount of royalties to be paid to the patent holder. The royalties are established by the IMPI after a hearing with the parties and they should be fair and reasonable.

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

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

The IP Law grants patent holders capacity to oppose exploitation of patented goods, such as importation (*see Question 5*). The linkage regulation prevents violation of patents by preventing approval of marketing authorisations for patented products.

The linkage system contain a Bolar-type exemption. This allows generic companies to apply for marketing authorisations and use patented materials to meet the regulatory requirements, three years before the expiry of a patent covering chemicals and eight years before for biologics.

Problems arise because the law and regulation of import permits for raw materials is silent about IP related controls and does not provide a reference to the *Linkage Gazette*. Basically, there are no guidelines or standards to bind COFEPRIS to review and take into consideration the amount of raw materials (active pharmaceutical ingredients) (APIs) that are authorised to be imported. The main concern is that recently, there have been an increasing number of permits to import patented compounds in bulk, that clearly exceed the justified amounts for clinical trials or experimental use.

As a result, patent holders have had to attempt different strategies to attack these violations of their IP rights, including patent infringement actions, where co-ordination between the patent and customs offices is not always ideal, and challenges against import permits issued by COFEPRIS. Measures by the authorities would be welcome to prevent the entry of infringing pharmaceutical substances into Mexico. Examples are:

- COFEPRIS using and observing the patent *Linkage Gazette* for the approval or rejection of import permits.
- COFEPRIS establishing the amount of APIs sufficient to comply with regulatory tests for marketing authorisation for follow-on products, denying imports of non-adequate amounts.
- COFEPRIS requiring importers to declare the destination of the imported products.
- IMPI clearly establishing through case law the differences between the sole experimental use and the Roche-Bolar exception.
- IMPI being careful when, on a case by case basis, it reviews what is an adequate amount to be imported for tests regarding a generic marketing authorisation application. In certain cases, a small amount of an API can represent the manufacturing of thousands of infringing products, which may end up in the grey and black market.
- Customs to take advantage of the information in the patent *Linkage Gazette*, to detect and stop eventual substances entering Mexico in violation of valid patents.

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

The ECFC published in 2010 the imposition of a fine on six pharmaceutical companies for anti-competitive practices in public tender proceedings by IMSS. This case remains under appeal (*see Question 13*).

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

The IP Law recognises the exclusive right of the title holder to prevent the importation of patented products or products obtained from a patented process. However, there are few cases involving IP and competition law regarding parallel imports.

In 2012, IMPI initiated the first border measures remedy against the importation of an active ingredient, due to the alleged administrative infringement of a patent. This is the first time border measures have been used based on a patent protecting pharmaceutical products. This was executed by IMPI in co-operation with the customs authorities, using a handheld near-infrared spectroscopy material analyser, which provided precise information on the inspected raw material and is standard equipment at borders.

Now, when a patent owner decides to proceed against an unauthorised importer of a medical product in Mexico, it should be possible to initiate a border measures injunction before IMPI, to stop introduction of the alleged infringing goods.

18. 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? How is such a licence made 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 whether or not it is recorded. However, to be effective against any third party, and to ensure the title holder has the use of the trade mark or patent, the licence must be recorded with IMPI (*Industrial Property Law*).

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

Recent transactions

- Participated in cases against the unconstitutionality and inefficiency of certain amendments to the Federal Law of Administrative Proceedings in Mexico, which have affected the venues for challenging resolutions by the Mexican Institute of Industrial Property.
- Sponsor of a proposal to modify the litigation system of industrial property, limiting the Mexican Institute of Industrial Property 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, published by the IP Media Group.*
- *Maximising IP rights in the life sciences industry, 2012, Intellectual Asset Management magazine issue 54, published by the IP Media Group.*
- *New Regulations Pending, 2011 edition of Life Sciences, Mexico Chapter: Biologic Drugs; published by 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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Areas of practice. Pharmaceutical law, IP litigation and enforcement.

Recent transactions

- Awarding of damages and lost profits regarding a patented blockbuster drug.
- Invalidity of a third party marketing authorisation related to a patented blockbuster drug.
- Microsoft Corporation: several cases of computer implemented inventions.
- McDonalds: several litigation proceedings against formative trade marks.

Languages. English, Spanish

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

Publications

- *Practical Law Life Sciences multi-jurisdictional guide 2014, Country chapter: Mexico.*
- *Pharmaceutical Trademarks 2013/2014 A Global Guide, World Trademark Review, Country chapter: Mexico.*
- *New rules to speed up administrative appeals. Managing Intellectual Property, September 2011.*
- *Scope of new specialised courts widened. Managing Intellectual Property, February 2011.*
- *IP Law amended. Managing Intellectual Property, June 2010.*
- *Make your case online. Managing Intellectual Property, IP Focus, 2009.*