World Trademark Review™

Pharmaceutical Trademarks 2017/2018

Mexico

Olivares & Cia SC

Victor Ramirez and Erwin Cruz

A Global Guide

INTELLECTUAL PROPERTY, CORPORATE & COMMERCIAL LAW

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Selection, clearance and registration

Regulatory bodies and requirements

The Industrial Property Law and the Industrial Property Law Regulations regulate trademarks in Mexico. Mexico has acceded to the following international treaties relevant to trademark protection:

- the Paris Convention for the Protection of Industrial Rights;
- the North American Free Trade Agreement;
- the Agreement on Trade-Related Aspects of Intellectual Property Rights;
- the Madrid Protocol for trademark registration; and
- the Trans-Pacific Partnership (TPP).

The exclusive right to a trademark is obtained through registration with the Mexican Institute of Industrial Property (IMPI).

All visible signs can be protected, provided that they are sufficiently distinctive and can distinguish the goods or services to which they apply from others in the same class (Article 89 of the Industrial Property Law). Once Parliament has enacted the amendments required by the TPP, non-traditional trademarks will be recognised.

New opposition system

The Industrial Property Law was recently amended to introduce an opposition system. As of the end of August 2016, the opposition system will work in parallel with the trademark prosecution system, as follows:

- The trademark application will be published in the *IP Gazette* no later than 10 working days after its filing date.
- Third parties can file observations against an application within one month (non-extendable) of publication. However, observations neither suspend prosecution of the application nor grant legal standing within this prosecution.
- IMPI will publish a list of applications for which observations have been received.
- Although IMPI is not obliged to assess observations, applicants can reply to these observations within one month of publication.

Regardless of observations, IMPI will decide on the grant or refusal of trademark applications.

Manufacturers must obtain marketing authorisation to sell any medicine or certain

medical devices. The relevant authority is the Federal Commission for Protection against Sanitary Risk (COFEPRIS), which approves the names of medicines – referred to as 'distinctive names'. In order to apply for a marketing authorisation, the distinctive name of the product must be pre-approved by COFEPRIS (Article 2(iv) of the Health Regulations).

Rules

The Health Law and the Health Regulations specify the requirements for distinctive names. The principal rules for the names of medicines are as follows:

- 'Distinctive name' means the name or trademark assigned to a pharmaceutical product in order to distinguish it from other similar products (Article 2(iv) of the Health Regulations).
- In use and marketing, medicines must be identified by their distinctive and generic names (Article 225 of the Health Law).
- The distinctive name must not refer to the composition of the product or its therapeutic action. Vaccines and biological products excepted, no indications may relate to diseases, syndromes, symptoms, anatomical data or physiological phenomena (Article 225 of the Health Law).
- A proposed distinctive name can be rejected if it is confusingly similar to a previous authorised name. Under the 'three-letter rule', the difference between the proposed name and the previous name should be at least three letters in each word to prove dissimilarity (Article 23 of the Health Regulations).
- A proposed distinctive name will be rejected if it is identical to the previous name of another approved medicine (Article 23 of the Health 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 of the Health Regulations).

Practical issues

There is no clear link between the Industrial Property Law and the Health Law and their regulations regarding conflicts between registered trademarks and marketing authorisations or distinctive names.

IMPI examiners usually consider the three-letter rule when analysing the similarity of pharmaceutical trademarks, although it is not binding on them. However, the Health Regulations do not require COFEPRIS to consider senior trademark registrations (for pharmaceutical products) when examining the similarity of distinctive names using its own software developed to apply the three-letter rule. This inconsistency has had unfortunate consequences, including contrary decisions of IMPI and COFEPRIS regarding the likelihood of confusion of trademarks and distinctive names.

Further, IMPI and COFEPRIS have different databases. The IMPI database comprises all trademark applications and registrations that have been filed with the agency or its predecessors, while the COFEPRIS database contains only the distinctive names allowed

Colours alone are unregistrable, 'unless they are combined or accompanied by elements such as symbols, designs or denominations that give them a distinctive character'. Thus, combinations of two or more colours can be registered as trademarks

for medicinal products, regardless of whether they are in use.

The COFEPRIS system enables pharmaceutical companies to obtain a pre-approval certificate for distinctive names, valid for 90 days, which is useful for any marketing authorisation. However, the system allows only 10 certificates to be granted per company and such certificates do not bind COFEPRIS, which can still reject marketing authorisation for a pre-approved distinctive name. Such rejection may be contested before the federal courts.

The new opposition system might be useful for pharmaceutical trademark holders to detect and raise objections before IMPI based on the health law regulations.

Confusion with INNs

Including international non-proprietary names (INNs) or their stems as part of pharmaceutical product trademarks creates conflicting situations.

On the one hand, Article 225 of the Health Law expressly forbids the use of pharmaceutical trademarks that clearly resemble INNs and Article 90(II) of the Industrial Property Law prohibits registration of generic names. Accordingly, IMPI has no legal basis for refusal of a trademark that comprises a stem or an INN and additional distinctive elements that make the trademark registrable as a whole.

However, INNs are generic and cannot be treated otherwise, which makes it impossible for IMPI to assess the likelihood of confusion between pharmaceutical trademarks and INNs.

Hence, IMPI faces a challenge in following the World Health Organisation's recommendations to safeguard the proper use of INNs and to avoid the registration of trademarks derived therefrom.

Non-traditional trademarks

Article 89 of the Industrial Property Law provides that only visible words, names and designs, including three-dimensional (3D) marks, are registrable as trademarks.

Under the Industrial Property Law, colours alone are unregistrable, "unless they are combined or accompanied by elements such as symbols, designs or denominations that give them a distinctive character". Thus, combinations of two or more colours can be registered as trademarks, regardless of the form or surface on which they are applied.

> **The Industrial Property Law establishes that the damages awarded to the owner of an infringed IP right should not be less than 40% of the sales of the infringing product at the consumer retail price**

Article 89 of the Industrial Property Law establishes that 3D signs have elements that can constitute a trademark and are thus registrable. However, a 3D mark must:

- not be in the public domain;
- not have fallen into common use;
- be sufficiently original to be easily distinguished; and
- not have a shape that represents the product or is required by its function.

Motion marks cannot be protected. Article 90(1) of the Industrial Property Law establishes that names, figures or forms expressed in a dynamic way cannot be registered as trademarks, regardless of whether they are visible.

The Industrial Property Law does not recognise marks comprising sounds, smells, tastes or textures, since they are not visible. However, Mexico has signed the TPP, whose provisions on non-traditional trademarks will require amendments to the legal framework once it enters into force.

Parallel imports and repackaging

Any import of medicines, health or pharmaceutical products – or raw materials for such products – must be approved by

COFEPRIS. Medicines must have marketing authorisation. Under certain circumstances (eg, clinical trials and orphan drugs), the import of a minimal quantity of products without marketing authorisation can be approved.

In relation to trademarks, parallel imports are allowed, provided that the product was legally introduced in the country of origin and the trademark is owned by the same company or group of companies in Mexico.

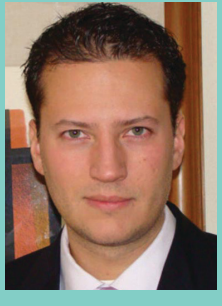
The packaging and labelling of pharmaceutical products are governed by the Health Law and its regulations and require approval by COFEPRIS. Altering or modifying the authorised packaging or labelling of approved pharmaceutical products can be considered a criminal offence (Article 464*ter* of the Health Law).

Anti-counterfeiting and enforcement

Trademark infringement action

A trademark registration can be enforced against alleged infringers in two ways:

- If the infringer uses a confusingly similar or identical trademark for identical or similar goods or services, an infringement



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Victor Ramirez obtained his law degree from the Pan-American University in Mexico City in 2000. He completed a postgraduate major in IP law at the same university in 2005 and attended the IP Summer Institute at the Franklin Pierce Law Centre in 2007.

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Mr Cruz is the author of several articles on patents, marketing authorisations and pharmaceutical regulatory compliance, including the Mexico chapter of *Practical Law, Pharmaceutical IP and Competition Law in Mexico 2014*.

action can be brought before IMPI.
- If the infringer uses an identical trademark for identical goods or services, a criminal action can be brought before the Attorney General's Office.

Infringement actions are filed before IMPI, which is an administrative authority rather than a court. Once admitted, IMPI serves notice of the infringement action on the alleged infringer, granting it 10 working days to reply.

On request, IMPI may impose provisional injunctions before the filing of an infringement claim or during the case.

Both the claimant and the alleged infringer must submit evidence at the time of filing or answering the claim. Subsequently, IMPI grants the parties a common term to file closing arguments. IMPI's decision is subject to appeal before the Federal Court of Tax and Administrative Affairs, whose decision can be further appealed before the circuit courts.

In order to prove infringement, the plaintiff may submit any type of evidence except confessional or testimonial evidence. The most common evidence used to prove infringement is an inspection of the alleged infringer's premises.

Infringers can incur penalties ranging from a fine of up to 20,000 times the minimum wage (around $100,000) to closure of their businesses (Article 214 of the Industrial Property Law). Repeated infringement is a criminal offence (Article 223 of the Industrial Property Law).

IMPI can impose a penalty and order the immediate cessation of the infringing activities. A civil action to claim damages in a civil court is possible once an IMPI decision of infringement is final and binding.

The Industrial Property Law establishes that the damages awarded to the owner of an infringed IP right should not be less than 40% of the sales of the infringing product at the consumer retail price.

Attorney General's Office

The federal prosecutor at the Attorney General's Office also investigates IP crimes and can use force during raids related to IP rights. However, it must obtain a search warrant from a federal court and can intervene only in cases involving the falsification of goods for which IP rights are held.

Proceedings begin with the mandatory filing of a special type of criminal complaint. In the context of an investigation, infringing goods can be seized without a search or warrant order if they are publicly available. However, if they are stored on private property, a search or warrant order must be obtained.

A raid may take place within 15 to 45 days, depending on the type of premises to be searched and its distance from Mexico City.

Indictments may be issued within 48 hours of execution of a search or warrant order if a suspect is arrested; it may take longer if the request relates to organised crime. If no suspect is arrested, an indictment may be issued within approximately two months. During that time, the seized goods are stored in government warehouses.

On completing the investigation, the federal prosecutor will bring the case before a federal court.

Trademark database at Customs

A database has been created, managed by Customs in coordination with IMPI, which contains the registered trademarks of owners interested in monitoring their rights at the 49 customs checkpoints at the country's borders, ports, bus and train stations and airports.

Regarding medicines, pharmaceutical substances, chemicals and active pharmaceutical ingredients (APIs), Customs' efforts are limited to detecting prohibited drugs and narcotics. The next step is to strengthen IP protection for patents within Mexico, particularly for those that protect pharmaceutical products.

Recently, Customs has collaborated with rights holders to detect and seize APIs based on IMPI-ordered border measures. Thanks to cooperation between Customs and IMPI, bulk border seizures of patented APIs have taken place.

Advertising

Regulatory framework

The primary legislation for the advertising of medicinal products is the Health Law and the Health Law Advertising Regulations, supplemented by COFEPRIS guidelines.

> **The Code of Good Promotion Practices requires that the information provided to healthcare professionals be accurate, balanced, fair and objective, and sufficiently complete for them to form their own opinion of the therapeutic value of the corresponding medicine**

Industry codes of practices complement these regulations. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued various self-regulatory codes, the latest of which came into force on April 1 2013. Affiliate members of the National Chamber of the Pharmaceutical Industry must adhere to the codes and CETIFARMA supervises compliance.

Further, the Advertising Council – comprising representatives from the Ministry of Health, the academic and scientific communities, the business sector, the media and consumer groups – also issues opinions.

Other general legislation may be relevant to the advertising of medicinal products – in particular, the Industrial Property Law and the Federal Law for the Protection of Consumers.

Further considerations

The Code of Ethics and Transparency of the Pharmaceutical Industry requires the provision of accurate and objective explanations of the characteristics, functions, advantages or disadvantages of pharmaceutical products or services.

Non-prescription medicines

According to the Health Law Advertising Regulations, only non-prescription medicines can be advertised to the general public, subject to approval by COFEPRIS. The media must require certified copies of the relevant marketing authorisations for the corresponding medicines before publishing or broadcasting related ads.

In February 2014 COFEPRIS issued detailed guidelines regarding the approval of ads for non-prescription medicinal products. According to these guidelines, COFEPRIS will not approve ads comparing products with the same therapeutic indication or questioning the quality of products with marketing authorisation.

Prescription medicines

Prescription medicines can be advertised to health professionals. However, this advertising can be done only through specialised media and must be based on medical prescription information.

The Code of Good Promotion Practices requires that the information provided to healthcare professionals be accurate, balanced, fair and objective, and sufficiently complete for them to form their own opinion of the therapeutic value of the corresponding medicine.

Surveillance

COFEPRIS can order the suspension of advertising activity in breach of the legal framework. The responsible party and the media channel must comply within 24 hours.

The penalties for failure to comply with the advertising rules are suspension of advertising activities by the responsible party or the media and a fine of between 2,000 and 16,000 times the minimum wage (around $10,000 to $80,000).

Generic substitution

Under the Health Regulations, a physician must prescribe medicines and biologics using

the INNs and may choose to indicate the preferred distinctive name. Thus, patients may receive from the pharmacist any product with the same active ingredient. At present, a proposal to amend the Health Law to prevent automatic switching from biologic innovators to biosimilars as a result of potential health issues is pending.

Online issues

Under the Health Regulations, medicines must be made available in authorised pharmacies and can be sold only to patients with a physician's prescription, especially antibiotics (except over-the-counter products).

Electronic advertising falls under the general advertising rules in Article 2 of the Health Regulations. At present, COFEPRIS is increasing its monitoring of online ads for medicinal products, which have been less stringently monitored than television or radio ads.

Pharmacies must obtain permission to operate on health grounds and other stores are forbidden from marketing prescription medicines.

The Code of Good Promotion Practices requires the adoption of measures to ensure that the promotion of prescription medicines on websites is accessible only to healthcare professionals. Such websites must have a warning stating that they may be used only by healthcare professionals allowed to prescribe drugs. **WTR**

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