Mexico

Contributing firm
Olivares & Cia SC

Authors
Victor Ramirez and **Erwin Cruz**

Selection, clearance and registration

Relevant bodies and requirements

Trademarks in Mexico are regulated under the Industrial Property Law and its regulations. Mexico is a party to a number of international treaties relevant to the protection of trademarks, including:

- 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; and
- the Madrid Protocol for trademark registration.

Industrialists, merchants and service providers can use trademarks in industry and commerce, or for the services that they provide (Article 87 of the Industrial Property Law). The exclusive right to use a trademark is obtained by registration before the Mexican Institute of Industrial Property (IMPI).

All visible signs can be protected, provided that they are sufficiently distinctive and can distinguish the products or services to which they apply (or are intended to be applied) from other products or services in the same class (Article 89 of the law).

Concerning health products, manufacturers must obtain a marketing authorisation to sell any medicine or certain medical devices. The authority in charge of granting marketing authorisations is the Federal Commission for Protection against Sanitary Risk (COFEPRIS), which approves the names of medicines – referred to as 'distinctive names'. Failure to submit an acceptable name will result in a bar on obtaining a marketing authorisation.

The specific requirements and rules regarding distinctive names are provided under the Health Law and its regulations. The basic rules regarding medicines' names are as follows:

- The term 'distinctive name' is understood to be the name or trademark assigned by the laboratory or manufacturer to its pharmaceutical products in order to distinguish it from other similar products.

Prior approval of the health authority and registration with the competent authorities are required (Section IV, Article 2 of the Health Law Regulations).

- Medications for use and marketing must be identified by their distinctive and generic names (Article 225 of the Health Law).
- The distinctive name must not make reference to the composition of the medicinal product or its therapeutic action. No indications are permitted in relation to diseases, syndromes, symptoms, anatomical data or physiological phenomena, except for vaccines and biological products (Article 225 of the Health Law).
- A proposed distinctive name can be rejected when it is confusingly similar to a prior authorised medicine name, in which case the difference between the proposed and prior medicine names should be at least three letters in each word (the 'three letters' rule – Article 23 of the Health Law Regulations).
- A distinctive name will also be rejected if the proposal is identical to a prior distinctive name of another approved medicine (Article 23 of the Health Law Regulations).
- The same distinctive name should be used only in the case of different pharmaceutical forms or different doses with the same principal active ingredient and registered by the same laboratory (Article 23 of the Health Law Regulations).

Although a legal definition of a distinctive name is provided under Section IV, Article 2 of the Health Law Regulations, in practice prior approval and registration with other relevant agencies such as IMPI are not required for the application and grant of the distinctive name before COFEPRIS.

As yet, there is no clear link between the Industrial Property Law and the Health Law and its regulations regarding conflicts between registered trademarks and marketing authorisations or distinctive names.

IMPI examiners usually take into consideration the three letters rule when analysing the similarity of trademarks for pharmaceutical products, although this rule is not binding on them. Further, under the Health Law Regulations COFEPRIS is not required to consider senior trademark registrations (for pharmaceutical products) when analysing the similarity of distinctive names by means of its own software developed to apply the three letters rule. This situation has had unfortunate consequences, such as contrary decisions issued by IMPI and COFEPRIS regarding the likelihood of confusion of trademarks and distinctive names.

Furthermore, 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 for medicinal products, regardless of whether such names are currently in use.

Since 2010 COFEPRIS has offered pharmaceutical companies the possibility of obtaining pre-approval through its website. If a three-letter overlap is detected, the proposed name will be rejected. If the distinctive name is approved, the system grants the user a certificate which is valid for 90 days and can be used for any marketing authorisation. The COFEPRIS system allows users to hold up to 10 certificates for distinctive names, which can be used by the company at any time while the certificates are valid. Once a certificate expires, the user can obtain new certificates.

However, such pre-approval certificates are not binding and COFEPRIS may still reject the distinctive name during the marketing authorisation procedure. Such rejection may be contested before the federal courts. Thus, a trademark linkage system between COFEPRIS and IMPI is required.

Confusion with international non-proprietary names

It is common practice for pharmaceutical companies to include international non-proprietary names (INNs) or stems as part of their trademarks, which creates conflicting situations for IMPI.

On one hand, Article 225 of the Health Law expressly forbids the use of pharmaceutical trademarks that clearly resemble an INN, and registration of generic names is prohibited under Section II, Article 90 of the Industrial Property Law. Accordingly, IMPI has no legal basis on which to refuse a trademark that

comprises a stem or an INN, provided that it includes additional distinctive elements that make the trademark registrable as a whole.

On the other hand, 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 has the challenge of following the World Health Organisation's recommendations to safeguard the proper use of INNs and avoid the registration of trademarks derived from them.

Non-traditional trademarks

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

Under the Industrial Property Law, colours alone are not registrable "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 subject to trademark protection and registration, regardless of the form or surface on which they are applied.

Article 89 expressly establishes that 3D signs have elements that can constitute a trademark and can thus be registered with IMPI. However, the Industrial Property Law establishes the following limitations on 3D marks:

- They are not in the public domain;
- They have not fallen into common use;
- They are sufficiently original to be easily distinguished; and
- The shape does not represent the product and is not imposed by the product's function.

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

Further, the law does not recognise marks comprising sounds, smells, tastes and textures, since these are not visible and consequently cannot be registered as trademarks in Mexico.

Parallel imports and repackaging

Any import of medicines, health or pharmaceutical products or raw material for such products must be approved by COFEPRIS, and a marketing authorisation is required. However, in certain circumstances (eg, clinical trials and orphan drugs), the import of a minimal quantity of products without a marketing authorisation can be approved.

Regarding IP rights, parallel imports are allowed in Mexico in relation to trademarks where both the product was legally introduced in the country of origin and the trademark is owned by the same company or a related company in Mexico.

The packaging and labelling of pharmaceutical products are governed by the Health Law and its regulations and must be approved 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).

Packaging and labelling requirements for pharmaceutical products include:

- a distinctive brand name;
- a generic name;
- a pharmaceutical form;
- the drug concentration;
- the formulation;
- the formula description;
- the dose;
- the mode of administration;
- conservation and storage information;
- precaution and warning legends, including risks in case of pregnancy;
- the marketing authorisation number;
- the batch number;
- the expiration date;
- the manufacturer's and, if applicable, distributor's information, including address; and
- the maximum price to the public.

All information on the label and packaging must be in Spanish.

Anti-counterfeiting and enforcement

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

- If the infringer is using a confusingly similar or identical trademark for goods or

services that are identical or similar to those covered by the trademark registration, an infringement action can be brought before IMPI.
- If the infringer is using an identical trademark for goods or services that are identical to those covered by the registration, a criminal action can be brought before the Attorney General's Office.

Infringement actions are filed before IMPI, which is an administrative authority, not a court. Once admitted, IMPI serves notice of the infringement action to the alleged infringer, granting it 10 working days to reply.

The Industrial Property Law also provides for provisional injunctions before the filing of an infringement claim or at any time during the case.

Both the claimant and the alleged infringer must file supporting evidence at the time of filing or answering the claim. Subsequently, IMPI grants parties a common term to file closing arguments, after which the case is ready for a decision. IMPI's decision can be appealed before the Federal Court of Tax and Administrative Affairs, and that court's final decision can be further appealed before the circuit courts.

In order to prove infringement, the claimant is entitled to file any type of evidence available, except confessional and testimonial evidence. The most common evidence used to prove an 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 (about $105,000) to final closure of the establishment (Article 214 of the Industrial Property Law). Repeated infringement is also considered a criminal offence (Article 223 of the Industrial Property Law).

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

Enforcement

In addition to the infringement action explained above, the federal prosecutor at the Attorney General's Office investigates alleged IP crimes. The federal prosecutor has the authority to use force during raids related to IP rights. However, he or she 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. While the federal prosecutor carries out an investigation, if they are available in public places the goods in question can be seized without the need for a search or warrant order. However, if the goods are stored on private property, a search or warrant order must be obtained in advance.

Once an investigation has been completed, the federal prosecutor should bring the case before a federal court.

A raid instigated by the federal prosecutor may take between 15 and 45 days, depending on the type of premises to be searched and their distance from Mexico City.

Indictments may be issued within 48 hours of execution of a search or warrant order if any suspects are detained; this term may be increased if the request relates to the investigation of organised crime. If no suspects are detained, an indictment may be issued within approximately two months. During that time, the seized goods are stored in government warehouses while further inquiries are made.

Advertising

Regulatory framework

Advertising of medicinal products and their trademarks in Mexico is governed mainly by the Health Law and its regulations. The regulations set out most of the specifics for authorisation proceedings and the characteristics of advertising. COFEPRIS enforces the provisions on advertising.

Opinions issued by the Advertising Council – which includes representatives from the Ministry of Health, the academic and scientific communities, the business sector, the media and consumer groups – also apply to the advertising of pharmaceutical products.

The Industrial Property Law and the Consumer Protection Law both contain provisions on advertising.

Further considerations

In Mexico, 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 medicines before publishing or broadcasting related adverts.

According to Article 43 of the Health Law Regulations, any visual or audio advertisement must feature the message "consult your physician", and must mention any precautions to be taken when use of the medicine represents a danger. The warning can either be displayed or mentioned orally, depending on the medium used for the advertisement.

Article 80 of the regulations lists the requirements governing the advertising of non-prescription medicines.

Prescription medicines can be advertised to health professionals. However, advertising directed to health professionals can be published only in specialised media and it must be based on medical prescription information.

According to the above, as well as the criteria currently applied by COFEPRIS, no advertisement directed to the general public may contain the brand or generic name of a product that requires a prescription, or any information related to such product. In general terms, ads for medicines should have the objective of informing the characteristics of the product, its therapeutic properties and the form of use.

The Health Law Regulations on advertising were amended on January 19 2012, granting COFEPRIS strong powers to require the media to remove any suspicious illegal ad within 24 hours and to impose a fine of up to 16,000 times the minimum wage ($83,000).

Generic substitution

Under Article 31 of the Health Law 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.

Online issues

Pursuant to the Health Law Regulations, medicines must be made available only in authorised drug stores and can be sold only to patients with a physician's prescription, especially antibiotics (with the exception of over-the-counter products).

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

All pharmacies must obtain permission to operate on health grounds, and the marketing of prescription medicines in other stores is forbidden.

In the event that any of the provisions of the Health Law or its regulations is breached by online advertising, the company responsible will be subject to the corresponding penalties.

COFEPRIS requires that websites sponsored by or belonging to pharmaceutical companies be secured with regard to prescription-only medicines. There are no specific rules describing the levels of security, but common practice has been to require the provision of a username and password (which can be granted to credited health professionals only) before access to information on prescription-only medicines is allowed.

Olivares & Cia SC

Olivares & Cia SC
Pedro Luis Ogazon 17, Col San Angel
01000 Mexico DF, Mexico
Tel +52 55 5322 3000
Fax +52 55 5322 3001
Web www.olivares.com.mx

Victor Ramirez
Associate
vrl@olivares.com.mx

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.

As an associate at Olivares & Cia, Mr Ramirez has extensive experience litigating industrial property matters, at first instance as well as at appellate level before the Federal Court of Tax of Administrative Affairs. He also regularly provides legal opinions on negotiations relating to IP matters and handles licence, assignment, franchise and technology transfer agreements. In addition, Mr Ramirez runs analyses and reports on the availability of trademarks, slogans and commercial names, as well as filing trademark applications.

Erwin Cruz
Associate
ecs@olivares.com.mx

Erwin Cruz holds a bachelor's degree from the National Autonomous University of Mexico (2006) and completed an IP specialisation programme there. He has also completed the contentious administrative proceeding specialisation programme offered by the Federal Court for Tax and Administrative Affairs.

His areas of practice are pharmaceutical law; IP litigation and enforcement. His recent transactions include handling several cases of computer-implemented inventions for Microsoft Corporation and the patent and infringement/invalidity of a blockbuster product. He has also contributed to several publications, including writing the Mexico chapter of the *Practical Law Multi-Jurisdictional Guide 2013 Life Sciences*.