

POR VÍCTOR RAMÍREZ

WORLD TRADEMARK REVIEW 2009

SELECTION, CLEARANCE AND REGISTRATION

RELEVANT BODIES AND REQUIREMENTS

Trademarks in Mexico are regulated under the Mexican Industrial Property Law (IPL) and its regulations.

Industrialists, merchants and service providers can use trademarks in industry and commerce, or for the services that they render (Article 87 of the IPL). The exclusive right to use a trademark is obtained through registration of the mark with the Mexican Trademark Office (IMPI).

All visible signs can be protected, provided that they are sufficiently distinctive and are able to 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).

Under this definition, olfactory and auditory trademarks cannot be protected. However, three-dimensional signs can be protected as trademarks, as these are visible signs. Article 90 provides a long list of prohibitions to the registration of signs as trademarks. That provision is the only legal source for rejecting a trademark application.

Mexico is a party to a number of international treaties relevant for the protection of trademarks, namely:

- the Paris Convention for the Protection of Industrial Rights;
- the North American Free Trade Agreement; and
- the Agreement on Trade-Related Aspects of Intellectual Property Rights.

CONFUSION WITH INNS

Although the IPL does not expressly refer to international non-proprietary names (INNs), names that are identical or confusingly similar to INNs may not be registered as trademarks, pursuant to Article 90(III) of the IPL. This provision states that registration will be refused for “the technical names or common usage [names] of the products or services the trademark intends to cover as well as words that, in the common language or commercial practice, have been converted into the usual or generic designation of the same”.

In the event that an INN or a name similar to an INN is registered as a trademark, any interested third party would be entitled to challenge such registration on the grounds of Article 90(III).

MARKETING AUTHORIZATION V TRADEMARK

Obtaining a marketing authorization from the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) for a pharmaceutical or drug name has become an important issue. The approval of the pharmaceutical or drug name is the main bar to obtaining a marketing authorization.

The Mexican Health Law Regulations provide as follows:

- A proposed drug name can be rejected if the name is confusingly similar to a prior authorized drug name. ‘Confusing similarity’ is found when at least three consecutive letters in the proposed name and the prior drug name are identical.
- A proposed drug name can be rejected if it is identical to a prior drug name, even if the application for the latter is still pending or the corresponding marketing authorization has been cancelled.

COFEPRIS’s decisions regarding pharmaceutical or drug names are independent from IMPI’s decisions regarding these names, which are treated as trademarks according to the applicable trademark law.

Unfortunately, neither the IPL nor the Health Law Regulations provide clear and specific guidance as to how to solve conflicts between registered trademarks and marketing authorizations.

IMPI examiners usually take into consideration the ‘three-letter rule’ under the regulations when analyzing the similarity of trademarks for pharmaceutical products, even though the rule is not binding on them.

Similarly, COFEPRIS is not bound by the Health Law Regulations to consider prior

trademark registrations (for pharmaceutical products) when analyzing the similarity of drug names.

Upon an application by a pharmaceutical company to approve a drug name, a COFEPRIS officer will run a database check against all previously approved names. The proposed name will be rejected if it matches an existing name by at least three consecutive letters.

This has led to contradictory decisions being issued by IMPI and COFEPRIS as regards the likelihood of confusion between some drug names.

The problem has become critical for pharmaceutical companies and has motivated the drafting of amendments to the Health Law Regulations.

PARALLEL IMPORTS AND REPACKAGING

Parallel imports are regulated only with respect to products bearing trademarks registered in Mexico. Under the IPL, parallel importation of these products is permitted, provided that the holder of the foreign registered trademark also holds the corresponding registration in Mexico.

In the case of patented products, parallel imports are not allowed. The patent holder in Mexico is therefore entitled to challenge any unauthorized importation through an infringement action.

In the case of medicinal products that are not protected by IP rights, parallel imports are allowed. However, the foreign manufacturer of the product must give its consent to the importation. This written consent must be submitted by the parallel importer to obtain permission for the importation of medicinal products from COFEPRIS.

The repackaging of pharmaceuticals is not expressly regulated by Mexican law. However, the packaging and labelling of medicinal products is governed by the Health Law Regulations regarding the sanitary control of products and services. COFEPRIS has the authority to monitor and enforce these regulations. Generally speaking, the packaging and labelling of all medicinal products must include:

- the generic or specific denomination of the product;
- the list of ingredients;
- the names and addresses of the manufacturer, importer, packer and distributor;
- instructions for the storage, preparation and administration of the product;

- the names of any component that could present a risk to consumers' health if the product is swallowed, applied or just manipulated;
- nutritional information;
- the product's expiry date;
- the lot identification number;
- a description of the conditions under which the product has been processed when it is associated with potential risks; and
- any other relevant warnings

A specific ruling for each kind of product determines the general sanitary information that the specific label should contain if – due to the size of the labelling or packaging, or due to the processing conditions – all the required information cannot appear. All the information on the label and packaging must be written in Spanish.

ANTI-COUNTERFEITING AND ENFORCEMENT

TRADEMARK INFRINGEMENT

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

- If the infringer is using a confusingly similar 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; or
- 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 or an infringement action can be brought before IMPI.

IMPI is not a court, but an administrative authority. If IMPI finds that an infringement has occurred, it will impose a fine on the infringer and order the latter to stop the infringing activities immediately. A trademark owner may file a civil action to claim damages before a civil court once IMPI's resolution declaring the infringement of a trademark registration has become final.

Bringing an infringement claim before IMPI is relatively simple. It begins with the filing of a formal written claim. Once IMPI has admitted the claim, it serves notice on the alleged infringer, giving it 10 days to answer. IMPI then decides on

the merits of the case.

Both the claimant and the alleged infringer must produce supporting evidence at the time of filing the claim or answering it. IMPI's decision can be appealed before the Federal Court of Tax and Administrative Affairs. The latter's decision can then be appealed to a circuit court.

To prove the infringement, the claimant is entitled to file any type of evidence available, except confessional and testimonial evidence. The most commonly used evidence to prove an infringement is an inspection of the premises of the alleged infringer.

The inspection is conducted by an IMPI inspector and usually takes place when:

- the notice of the claim is served on the alleged infringer; and/or
- the order imposing a preliminary injunction on the alleged infringer is issued.

The IPL also provides for provisional injunctions before the filing of the infringement claim or at any time during the case.

ANTI-COUNTERFEITING

LEGAL FRAMEWORK

Although a number of international treaties and the Mexican Constitution touch on aspects of anti-counterfeiting law, the main relevant domestic laws are:

- the IPL;
- the Federal Criminal Law; and
- the Customs Law.

CRIMINAL PROSECUTION

The federal prosecutor at the Attorney General's Office investigates alleged IP crimes with the support of the Federal Investigations Agency and the federal police. The federal prosecutor has the authority to use force during raids related to IP rights.

However, the federal prosecutor must obtain a search warrant from a federal

court and can intervene only in cases regarding the falsification of goods for which IP rights are held.

The proceedings begin with the mandatory filing of a special type of criminal complaint (known as a 'querrela'). Because IP rights can be enforced only by their owners, rights holders must maintain good channels of communication with the relevant authorities.

While the federal prosecutor carries out an investigation, the goods in question can be seized, without the need for a search or warrant order, if they are available in public places. 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 will indict 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 that must be searched and their distance from Mexico City. Indictments may be issued within 48 hours of the execution of a search or warrant order if any suspects are detained; this term may be increased if the request relates to an organized crime investigation. 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 General Health Law and the Health Law Regulations regarding advertising.

Even though the regulations cannot go beyond the scope of the Health Law, they contain most of the specifics of authorization proceedings and the characteristics of advertising.

The authority in charge of enforcing the provisions on advertising is COFEPRIS, which is part of the Ministry of Health.

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 consumers' groups – also apply to the advertising of pharmaceutical products.

Finally, the IPL and the Federal Law for the Protection of Consumers both contain provisions regarding advertising.

FURTHER CONSIDERATIONS

In Mexico, it is possible to advertise nonprescription medicines to the general public, subject to prior authorization by COFEPRIS. However, according to Article 43 of the Health Law Regulations regarding advertising, any visual or audio advertisement must feature the message “Consult your physician”.

In addition, an advertisement should warn of any danger in using the drug in the event of an existing pathology. The warning can be either displayed on the screen or mentioned orally, depending on the medium used for the advertisement.

Furthermore, Article 44 of the regulations establishes restrictions when the medicine advertisement:

- is presented as a definitive solution in the preventive, curative or rehabilitation treatment of a specific disease;
- suggests use of the drug to treat different symptoms than those specified in the marketing authorization for the product;
- alters the dosage authorized by COFEPRIS;
- promotes the drugs through draws, raffles, contests or any other event involving chance;
- uses statements or testimonies that can confuse the public or are unfounded;
- uses cartoons that can confuse and entice minors to use the product; and
- does not display the warnings mentioned in the regulations.

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

In accordance with Article 310 of the General Health Law, only non-prescription medicines can be advertised to the general public and the objective of such advertising must be to inform the public of the characteristics of the product, its therapeutic properties and the form of use.

According to the above and to the criterion 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.

GENERIC SUBSTITUTION

Generic substitution of pharmaceutical drugs in Mexico is governed primarily by the Patent Law and the Health Law Regulations.

'Generic substitution' means providing consumers with a bioequivalent to the patented pharmaceutical, at a lower cost than is otherwise available.

To obtain an authorization to market generic pharmaceuticals, applicants must show that the following elements of the drug are the same as or equivalent to the innovator drug:

- the active ingredient;
- the pharmaceutical form;
- the concentration;
- the potency;
- the means of administration and the specifications; and
- the dissolution profile and bioavailability.

ONLINE ISSUES

The Health Law and its regulations are silent on the marketing of medicinal products over the Internet. However, all pharmacies must receive permission to operate on sanitary grounds and the marketing of medicinal products in other stores is forbidden.

The health authorities do not monitor internet advertisements on the same level as they do television or radio advertisements. Thus, there are few examples of actions taken by COFEPRIS in relation to online advertisements. Nevertheless, in the event that any of the provisions of the Health Law or its regulations are breached by online advertising, the company responsible would 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 these levels of security, but common practice has been to include a requirement to provide a username and password (which can be

granted to credited health professionals only) before access to information on prescription-only medicines is allowed.

Source: World Trademark Review 2009.