Pharmaceutical Trademarks 2021

LEXOLOGY
Getting The Deal Through

Mexico

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OLIVARES

OVERVIEW

Legislation

1 What is the primary law governing trademarks in your jurisdiction?

The Industrial Property Law (IP Law) and its Regulation regulate trademarks in Mexico. Mexico has acceded to the following international and multilateral treaties relevant to trademark protection:

- the Paris Convention for the Protection of Industrial Property Rights;
- the United States-Mexico-Canada Agreement;
- the Agreement on Trade-Related Aspects of Intellectual Property Rights; and
- the Madrid Protocol for trademark registration.

On 1 July 2020, and as a result of the entry into force of the United States–Mexico–Canada Agreement (USMCA), which replaces the North American Free Trade Agreement (NAFTA), the new Federal Law for Protection of the Industrial Property was enacted and came into force on 5 November 2020.

Agencies

2 Which agency is responsible for the grant and registration of pharmaceutical trademarks?

The exclusive right to a trademark is obtained through registration with the Mexican Institute of Industrial Property (IMPI). All traditional and non-traditional trademarks (eg, scent, sound marks, holograms, etc), as well as trade dress 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 172 of the new IP Law).

Regulators

3 What are the relevant national and international regulatory bodies and requirements that need to be considered when clearing a pharmaceutical trademark?

Manufacturers must obtain marketing authorisation to sell any medicine or certain medical devices. The relevant authority is the Federal Commission for Protection against Sanitary Risks (COFEPRIS), which approves the names of medicines, referred to as 'distinctive names' in the Health Law and its regulations. To apply for marketing authorisation, the distinctive name of the product must be pre-approved by COFEPRIS (article 2, section IV of the Health Supplies Regulation).

The Health Law and the Health Supplies Regulation 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 to distinguish it from other similar products (article 2, section IV of the Health Supplies 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 will be rejected if it is identical to the previous name of another approved medicine (article 23 of the Health Supplies Regulation).
- 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 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 of the Health Supplies Regulation).

There is no clear link between the IP 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 Supplies Regulation 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 contradictory decisions by IMPI and COFEPRIS regarding the likelihood of confusion of trademarks and distinctive names.

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

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 that COFEPRIS may ultimately consider is unacceptable. This rejection may be contested before the federal courts.

Non-traditional trademarks

4 | What non-traditional trademarks are available in your jurisdiction and how are they registered?

Pursuant to the IP Law amendments effective from 10 August 2018, trademark protection for non-traditional trademarks (eg, scent and sound marks, certain animated marks such as holograms and trade dress) have been incorporated for the first time in Mexico. Likewise, acquired distinctiveness will be recognised as an exception to the absolute grounds for refusal established in law.

The IP Law establishes that a trademark should be understood as 'any sign perceptible by the senses'. The only condition for the protection of such signs is that these are 'susceptible of being represented in a way that allows it to determine the clear and precise object of protection'. No specific requirements have been issued at present for non-traditional trademarks, but the regulations to the new IP Law are yet to be published.

Cannabis-derived products

5 | Does your jurisdiction allow the registration of cannabis-derived products?

Yes, the Health Law already provides for the use of cannabis for pharmaceutical purposes. However, the issuance of the regulations that will define the rules applicable to the use of cannabis in the pharmaceutical and recreational grounds is currently pending, which are expected to include specifications regarding its plantation, harvesting, industrial transformation, labelling, advertising, distribution, commercialisation, possession and consumption.

PARALLEL IMPORTS

Regulation

6 | What are the rules governing parallel imports of pharmaceutical goods?

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. 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 can be considered a criminal offence.

Strategies against parallel imports

7 | What strategies are available to police and enforce against parallel imports?

In accordance with the IP Law, and subject to the analysis of the particular circumstances, there is the possibility to file infringement actions on the grounds of unfair competition. However, the parallel importations (grey market goods) are not limited regarding trademarks and copyrights.

ANTI-COUNTERFEITING AND ENFORCEMENT

Types of proceedings

8 | What types of legal or administrative proceedings are available to enforce against infringing products?

A Trademark Enforcement 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.

Customs may collaborate with rights holders to detect and seize APIs based on IMPI-ordered border measures, initiated by the right holder. Thanks to cooperation between Customs and IMPI, bulk border seizures of patented APIs have taken place.

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

Remedies

9 | What are the available remedies for infringement?

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

On request, IMPI can impose provisional injunctions before the filing of an infringement claim or during the prosecution of the case. In case the right holder decides to proceed with a provisional injunction, they will have 20 days after imposing these, to file the administrative infringement action.

The claimant and the alleged infringer must both submit evidence at the time of filing or responding to the claim. Subsequently, IMPI grants the parties a common term to file closing allegations. IMPI's decision is subject to appeal before the Federal Court for Administrative Affairs, whose decision can be further appealed before the Circuit Courts.

Infringers can incur penalties ranging from a fine of up to 250,000 units of measurement and updating (UMAs), in force at the time the offense is committed per infringement conduct, to closure of their businesses (article 388 of the IP Law).

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

Damages may be claimed at the choice of the affected titleholder once the administrative procedure has been completed, with:

- the Mexican Institute of Industrial Property (IMPI) though a special proceeding. Once IMPI has declared an administrative infringement and this decision is enforceable, the affected titleholder may file a damages claim as well as the corresponding quantification, exhibiting relevant evidence; and
- the civil courts, in accordance with the provisions of common legislation and without the need for prior declaration.

Furthermore, The Federal Prosecutor at the Attorney General's Office also investigates IP crime, and can implement several injunctions such as the implementation of raids related to IP rights crimes.

However, the right holder has to file a criminal complaint to initiate a criminal action, so the Federal Prosecutor can request the raid order from a criminal judge, only in cases involving the counterfeiting of goods for which IP rights are held.

As previously mentioned, the criminal complaint filed by the rightholder, can be in the context of an investigation, and in certain cases, counterfeit goods can be seized without the implementation of a raid, but through a street seizure if they are publicly available. However, if they are stored on private property, a search or warrant order must be obtained from the criminal judge.

A raid may take place within 20 to 45 days, depending on the type of premises to be raided and its distance from the Attorney General's Office in which the right holder initiated the criminal action.

Indictments may be issued within 48 hours of the execution of a search or warrant order if a person who is considered as responsible for the commission of the crime is arrested. If during the raid, the Federal Prosecutor or the Police did not identify any responsible party, the criminal investigation will continue until the authority obtains all the elements to indict the case. This could take between two months and two years. During all this time, the seized goods are stored in government warehouses.

Once the criminal investigation is indicted, the criminal judge will proceed with the first revision of the file to identify if all the elements and confirm that the case is complete to move forward with a criminal trial.

Border enforcement

10 | What border enforcement measures are available to halt the import and export of infringing goods?

We can implement criminal actions or administrative actions.

Mexican Customs are not empowered to proceed with the seizure of products, therefore, they will only initially seize the alleged infringing products during a five-day period, until the authority receives the notification from IMPI or from the Attorney General´s Office that a border measure injunction or a criminal case has been initiated.

In the case of the administrative actions (IMPI), it can be grounded on the infringement of trade dress, unlawful competition, use of identical or similar trademarks, copyrights, patents, designs, among other IP rights. This will be the most complete action that a rightholder can initiate because we can implement said legal actions based on several IP rights.

However, regarding criminal cases, we can only proceed when we identify an identical use of trademarks and copyrights. The type of action that the rightholder could present will derive from the alert received by Customs and the enforceable rights in Mexico.

Online pharmacy regulation

11 | What rules are in place to govern online pharmacies?

Under the Health Regulations, medicines must be made available through authorised pharmacies and can only be sold 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. COFEPRIS has been increasing its monitoring of online ads for medicinal products, which traditionally 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 implementation of measures to ensure that the promotion of prescription medicines on websites is accessible only to healthcare professionals. Such websites must carry a warning stating that they may be used only by healthcare professionals allowed to prescribe drugs.

Recent cases

12 | What are the most notable recent cases regarding the enforcement of pharmaceutical marks?

Our client identified the existence of a company that was importing and selling counterfeit products and grey market drugs, bearing the trademarks of the client, and the active ingredient duly protected by a patent in Mexico.

Derived from the above, our team developed a programme in which we contacted several authorities to be aware of the possible risks that we will be facing in case of the importation and commercialisation of the counterfeit and gray market goods, mainly to remove the risk to society.

Due to the health risk that these types of products involve, we proceed to file before the Federal Commission for Protection against Sanitary Risks (COFERPRIS) a complaint, for the authority to proceed with the investigation of the products. Based on the complaint, the authority proceeded to implement a health risk alert regarding said products.

Finally, we implemented an administrative infringement action against said company, and their drugstore, based on the infringement of the trademarks of the rightholder, to proceed with a legal action.

These types of cases should be attacked, from our experience, through multidisciplinary actions.

ADVERTISING

Regulatory bodies

13 | Which bodies are responsible for oversight of pharmaceutical advertising in your jurisdiction (and what are their powers)?

The primary legislation for the advertising of medicinal products is the General Health Law (Ley General de Salud) (HL), and its Regulations (HLR). These norms are supplemented by guidelines published by the Regulatory Agency, the Federal Commission for Protection against Sanitary Risks (COFEPRIS). This agency is part of the Ministry of Health and controls the advertising of medicinal products. Industry Codes of Practices complement this regulation. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory instruments.

The latest versions of these Codes have been in force since 1 April 2013. Affiliate members of the National Chamber of the Pharmaceutical Industry are required to follow these Codes. CETIFARMA supervises members' and adherents' compliance. Additionally, other general legislation may be relevant for the advertising of medicinal products, particularly, the Federal Law for the Protection of Consumers and the Industrial Property Law. The most important rule to be considered in connection to consumer protections is that information or advertising relating to pharmaceuticals disseminated through any medium must be true, verifiable and free of text, dialogue, sounds, images, trademarks, denominations of origin and other descriptions that induce or may induce an error or confusion because they are deceptive or abusive.

CETIFARMA's codes further require the provision of accurate and objective explanations of the characteristics, functions, advantages and disadvantages of pharmaceutical products and services.

Advertising rules

14 | What specific rules are in place regarding the advertising of pharmaceutical products?

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.

According to its internal guidelines, COFEPRIS does 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 healthcare professionals. However, this advertising can be done only through specialist 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.

Monitoring

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 up to 16,000 times the minimum wage (approximately US$76,800).

GENERIC SUBSTITUTION

Legality

15 | Is generic substitution permitted in your jurisdiction?

Yes, under the Health Regulations, a physician must prescribe medicines and biologics using their INNs and may choose to indicate the preferred distinctive name. Thus, patients may receive from the pharmacist any product with the same active ingredient.

A review of possible mechanisms to prevent automatic switching from biologic innovators to biosimilars in view of potential health issues is pending.

Additionally, promotional activities to consumers should inform the patient or consumer about the properties of the medicines he or she is using, of the importance of concluding the treatment prescribed by the physician, and about the risks of unwittingly substituting the prescribed medicine for another one without proper medical supervision.

Regulations

16 | Which regulations govern generic substitution by pharmacists of brand-name drugs?

The Health Supplies Regulation establishes the provisions applicable to the prescription of drugs.

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UPDATE AND TRENDS

Key developments and future prospects

17 | What were the key judicial, legislative, regulatory and policy developments of the past year in relation to the protection and enforcement of pharmaceutical trademarks? What are the prospects for future developments?

On 8 March 2018, 11 countries signed the free trade agreement formerly known as the Trans-Pacific Partnership, which has been renamed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The signing members are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. The CPTPP includes several provisions that will certainly have a positive impact in terms of enforcement and litigation.

On the other hand, Mexico, Canada and the United States of America signed on 30 November 2018 the United States–Mexico–Canada Agreement known as USMCA, which also includes favourable amendments related to pharmaceuticals and regulatory matters and entered into force on 1 July 2020.

On 1 July 2020, and as a result of the entry into force of the USMCA, which replaces the North American Free Trade Agreement, the new Federal Law for Protection of the Industrial Property was enacted.

The new IP Law, represents an important legislative change, as it is aimed at matching the domestic law with the standards set by the new trade and cooperation agreements signed by Mexico in recent years, and it came into force on 5 November 2020.

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