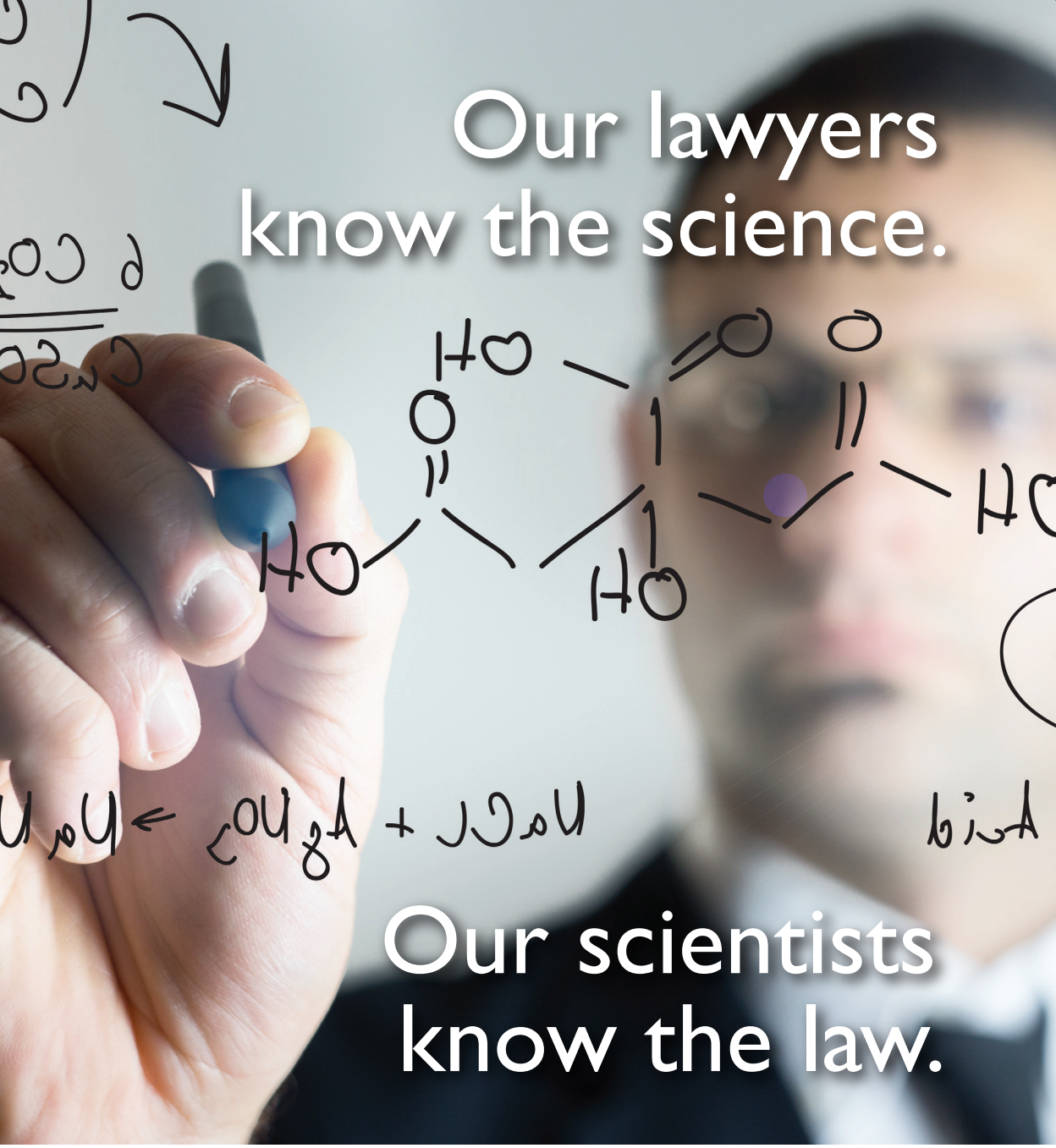

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Mexico

OLIVARES

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Selection, clearance and registration

Regulatory bodies and requirements

The Industrial Property Law (IP Law) and its regulations 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.

The exclusive right to a trademark is obtained through registration with the Mexican Institute of Industrial Property (IMPI). All visible and non-visible signs (eg, scent and sound marks), as well as for certain animated marks (eg, holograms) and 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 89 of the IP Law).

Opposition system

The opposition system works in parallel with the trademark prosecution system. Once an application is filed before IMPI, it is published for opposition in the *Industrial Property Gazette* within the next 10 working days, granting any interested party a one-month term for opposing the registration. If an opposition is filed, it will also be published in the *Gazette* within 10 working days after the opposition deadline, granting the applicant a one-month term, as of the publication date, for filing its response.

In accordance with the new amendments to the law (effective since 10 August 2018), IMPI should consider the opposition when conducting its own official examination and issue a decision on the opposition *per se*.

Marketing authorisation

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 the Health Law and its regulations. 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).

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 will be rejected if it is identical to the previous name of another approved medicine (Article 23 of the Health Regulations).
- 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 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 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 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 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 that COFEPRIS may ultimately consider is unacceptable. Such rejection may be contested before the federal courts.

'Distinctive name' means the name or trademark assigned to a pharmaceutical product in order to distinguish it from other similar products

> **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**

The new opposition system might be useful for pharmaceutical trademark owners to detect and raise objections before IMPI based on the Health Law and its regulations.

Confusion with INNs

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

The Health Law (Article 225) expressly forbids the use of pharmaceutical trademarks that clearly resemble INNs and the IP Law (Article 90(II)) 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.

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.

IMPI thus 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

Pursuant to the IP Law amendments, trademark protection for non-traditional trademarks (eg, scent and sound marks, certain animated marks such as holograms, and trade) 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.

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 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 (Article 464*ter* of the Health Law).

Anti-counterfeiting and enforcement

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.

Customs may collaborate 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.

> 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

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.
- 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 action

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.

Both the claimant and the alleged infringer must 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 20,000 times the minimum wage (around $100,000) to closure of their businesses (Article 214 of the IP Law). Repeated infringement is a criminal offence (Article 223 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% of the sales of the infringing product at the consumer retail price. This provision is currently under review by the Supreme Court.

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.

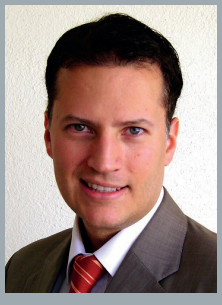
On completing the investigation, the federal prosecutor will bring the case before a federal court.

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.

Industry codes of practice complement these regulations. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued various self-regulatory codes. Affiliate members of



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Victor Ramirez joined OLIVARES in 1999 and completed a postgraduate major in IP law at the Pan-American University in Mexico City in 2005. He attended the IP Summer Institute at the Franklin Pierce Law Centre in 2007.

Mr Ramirez's work at OLIVARES focuses on counselling, lobbying and prosecuting administrative proceedings on IP and regulatory matters such as marketing, advertising and labelling issues before government agencies such as the Mexican Trademark and Patent Office, the Federal Commission for Health Risks and the Consumer's Attorney General Office.

He is also an experienced litigator, assisting clients from a number of industries to challenge before the courts the inspections, infringement proceedings and seizures or fines imposed by government agencies.

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Erwin Cruz has been helping clients to add value to their businesses and projects in Mexico since 2008, when he became part of the OLIVARES life science law group. He achieves this not only by obtaining exclusive rights for clients, but also by developing and successfully implementing strategies to enforce these rights and fair trade rules against potential infringers.

Mr Cruz provides highly qualified regulatory assistance related to marketing, labelling and advertising. He has extensive expertise and has written several articles about litigation and regulations relating to the pharma, agro and software industries. He regularly participates in international and national conferences.

the National Chamber of the Pharmaceutical Industry must adhere to the codes and CETIFARMA supervises compliance. The Advertising Council also issues opinions.

Other general legislation may be relevant to the advertising of medicinal products – in particular, the Federal Law for the Protection of Consumers and the IP Law. The most important rule to be considered in connection to consumer protections is that information or advertising relating to pharmaceuticals that is 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.

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 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.

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

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.

Online issues

Under the Health Regulations, medicines must be made available through authorised pharmacies and can be sold to patients only 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 adoption 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.

Domain names

As in the rest of the world, in Mexico the protection of domain names is a new issue that requires attention, as it has triggered legal questions of many sorts.

For example, one common question is whether a domain name can be protected as a trademark. In principle, it is possible, as domain names are capable of distinguishing

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products or services that originate from the same source and pertain to the domain name holder. Domain names do not merely serve as URLs. Of course, to qualify for trademark protection, the domain name – or at least the second portion thereof – must meet the principles and general standards of the IP Law and be duly registered with IMPI.

Local Dispute Resolution Policy action may apply regarding cybersquatting. It is a variation of the Uniform Domain Name Dispute Resolution Policy established by the Internet Corporation for Assigned Names and Numbers and the World Intellectual Property Organisation. WTR

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