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Mexico

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REGULATORY OVERVIEW

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

The main regulatory framework in relation to medical products is set out in the following federal laws:

- General Health Law (*Ley General de Salud*) (LGS).
- Health Law Regulations (*Reglamento de Insumos para la Salud*) (RIS).
- Official Mexican Standards (*Norma Oficial Mexicana*) (NOMs).

Regulatory authorities

The authority responsible for enforcing the regulatory framework in relation to medicines is the Federal Commission for Protection against Sanitary Risk (*Sitio Oficial de la Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS) (*see box, The regulatory authority*), which is part of the Ministry of Health (*Secretaria de Salud*). See *Question 35*.

Biotechnology and combination products

A decree was published in October 2011, modifying several provisions of the Health Law Regulations. The amendments concern the approval of biologic drugs, an area which was previously poorly regulated. The main points of interest are as follows:

- The provision included in the law stating that Mexico will allow for the approval of follow-ons as "biocomparables" is regulated in more detail.
- Commonly, a biocomparable drug will make reference to a previously registered innovator drug. If the innovator drug has not been authorised in Mexico, a previously registered biocomparable drug can now be used as a reference. The significance of this provision is that a biocomparable drug can be the first drug of its kind in Mexico, rather than the innovator drug, in the event that a developer delays a request for approval.
- Concerning prescription requirements, a provision now states that prescriptions must contain the International Nonproprietary Name (INN) of the active ingredient. The commercial name is optional.
- Clinical trials for innovator biologics must take place in Mexico in all cases where the drug will be manufactured in Mexico.
- For drugs manufactured abroad, the Ministry of Health can request that a clinical trial take place in Mexico, when a Biologic Products Committee considers that this step is necessary.
- In the case of the approval of biocomparable drugs, preclinical and clinical trials can be requested by the Ministry of Health (the rules governing this request procedure will be published in specific rules).
- The reach of biocomparability clinical trials will now be supported by evidence of active ingredient characterisation, and, as that ingredient characterisation improves, the number of trials required will decrease.
- An eight-year Bolar type exemption is included concerning requests for approval of biocomparables when an innovator drug is covered by a patent (the Bolar exemption enables the data from studies, tests and trials of the innovator drug to be used in the approval process of biocomparables without this use amounting to patent infringement).
- Once an authorisation request for either innovators or biocomparables has been approved by the corresponding committee and submitted, the Federal Commission for Protection against Sanitary Risks (COFEPRIS) has a 180-day period to make a decision on the application (it also has the option to issue a single request for additional information, which must be complied with in 100 days from the date of the request). Upon the expiration of these periods, applications are considered denied unless they have been specifically approved.

Although industry participants welcome these amendments, specific rules to approve biocomparables are still pending. Further, there is currently no indication of a data protection period, as was initially expected since Mexico has not yet implemented provisions concerning data protection for chemical drugs.

PRICING AND STATE FUNDING

2. What is the structure of the national healthcare system, and how is it funded?

The Ministry of Health:

- Governs the health system in Mexico.
- Manages social security and health insurance.
- Determines the National Formulary for the list of basic drugs.

The Mexican healthcare system comprises public and private insurers, out-of-pocket payments and informal arrangements.

The major public segments of the Mexican healthcare system are:

- Social Security (*Instituto Mexicano del Seguro Social*) (IMSS) (for the self-employed and employees in private companies).

- Social Security for State Workers (*Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado*) (ISSSTE).
- *Seguro Popular* (SP). This is a programme for the state workforce, created in 2004 as part of a strategic reform to the LGS, providing a public insurance scheme for those not covered by social security and other formal arrangements. The *Seguro Popular* was created to cover people with lower incomes. The federal government pays 70% of the annual family premium, states provide 20% and participants provide 10%.

The Department of Defence provides health coverage for members of the military.

Private health insurance generally covers professional, executive and higher levels of the private sector. Enrolment in private health insurance has increased considerably over the last five years.

The public health sector currently faces its worst ever financial crisis and has implemented measures to contain costs by using price reductions and encouraging competition (*see Question 35*).

3. How are the prices of medicinal products regulated?

Price control in the private sector is based on a scheme of self-regulated maximum retail price (MRP) covering patented products, overseen by the Ministry of Economy. Pharmaceutical companies' participation is voluntary. Under the price control each product's MRP must not exceed an international reference price, estimated as the average price in six major markets, plus a market factor. There are no established sanctions for violations of the MRP.

In 2008, the government created the Committee for the Negotiation of Drug Prices (CNDP) to:

- Support public acquisitions through a process of negotiation transparency between public insurers and pharmaceutical companies.
- Determine the cost-benefits ratio of new medicines and therapies in relation to their prices and those of other products in the market.

4. When is the cost of a medicinal product funded by the state or reimbursed to the patient? How is the pharmacist compensated for his dispensing services?

The IMSS is the largest public sector purchaser of drugs. Public sector purchases are made through public tender processes. The CNDP analyses the effectiveness of drugs and relevant therapeutic alternatives, and the feasibility and implications of an eventual substitution with equivalent medicines.

The CNDP also conducts an economic evaluation of the cost-effectiveness of patented medicines compared with potential substitutes. Drug payments by the government (mainly in the IMSS) derive from the obligatory fees paid by both employees and employers. However, federal government subsidies are necessary in all segments of the public health system at the federal and state levels.

In the private sector, the majority of payments are made on an out-of-pocket basis. Private insurers are currently improving the level of pharmaceutical coverage as the private market in medicines has grown considerably in the last six years.

MANUFACTURING

5. What is the authorisation process for manufacturing medicinal products?

Application

COFEPRIS grants medical licences.

Conditions

There are two main NOMs that oversee good manufacturing practice in the industry. These are reviewed every five years and regulate and provide guidelines and standards for:

- Workforce conditions in the plant (including responsibilities, uniforms, medical examinations and so on).
- Legal and technical documentation.
- Facilities requirements.
- Manufacturing control and protocols.
- Packaging.
- Equipment.
- Destruction and elimination of waste.

Restrictions on foreign applicants

Historically, COFEPRIS only granted medical licences to manufacturers in Mexico, due to a lack of resources to inspect production processes abroad. However, in 2008 the Mexican government eliminated the plant inspection requirement, which was replaced by a certificate of good manufacturing practice issued by the authority of the country of origin, with inspection visits only in high-risk cases.

Key stages and timing

COFEPRIS ensures the NOM is enforced when a facility begins production and thereafter at least every two years.

Fee

The fee is approximately US$6,000 (as at 1 November 2011, EUR1 was about US$1.4).

Period of authorisation and renewals

Drug manufacturers must renew their licence every five years, subject to the relevant tests, including the presentation of a certificate of good manufacturing practice.

6. What powers does the regulator have in relation to manufacturing authorisations?

Monitoring compliance

COFEPRIS has a Permanent Pharmacovigilance Programme. This is based on the information on possible adverse effects of the drugs given by:

- Doctors and physicians, on a voluntary basis.
- The pharmaceutical companies that manufactured the products and those who conduct clinical trials, who must both report any health risks.

Under the Health Law Regulations and the Official Mexican Standards, COFEPRIS's monitoring is focused, among other things, on the following:

- Ensuring compliance with good manufacturing practices and standard operating procedures.
- Ensuring the activities do not exceed the limits set by the authorisation and do not differ from those activities which are authorised.
- Ensuring the performance of validation analysis of the manufacturing processes and systems involved.

Imposing penalties

COFEPRIS is entitled to implement preliminary measures that are in the interests of the public health, for example:

- The seizure of products.
- Ordering the partial or total suspension of activities, services or advertisements.

An *ex officio* proceeding can be initiated to review a suspected health risk concerning an authorised product, and the licence holder must then in turn file their response to the initial request for review.

COFEPRIS can determine to revoke medical licences or authorisations, and/or impose sanctions ranging from a fine of up to 16,000 times the minimum wage (approximately US$70,000) to closure of the establishment.

The imposition of administrative sanctions does not exclude the application of criminal sanctions.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials are regulated by the Regulation for Health Investigation (RHI), which is enforced by the Ministry of Health and COFEPRIS.

Authorisations

Clinical trials require:

- Authorisation from the head of the health institution where the clinical trial will take place.
- Ministry of Health supervision.
- A favourable opinion from the Committee of Investigation, Ethics and Biosafety.

Consent

The subject's consent to the clinical trial must be established in a formal written document, witnessed before two witnesses. That written document must also show that the subject:

- Has been provided with full information about the nature and risks of the clinical trial.
- Is exercising free will in taking part in the clinical trial.

The information provided to the subject must be detailed and accurate.

Trial pre-conditions

There is no express obligation that the subjects of clinical trials must be insured. However, the institution running the clinical trial must provide medical assistance and financial indemnification for damages caused.

Under Article 63 of the RHI, when there is sponsorship or other forms of remuneration for the clinical trial, measures must be put in place to ensure that there is no conflict of interest between the principal researcher's duties to:

- Protect the rights of the subjects of the trial.
- Maintain accurate results.
- Allocate resources.

Procedural requirements

The RHI also provides the guidelines and standards for the trial protocol, including rules concerning documentation, compilation, confidentiality and reports.

Under the Health Law Regulations and Health Technical Norms, any clinical trial must be conducted following ethical guidelines and must always respect the dignity, rights and welfare of the human being.

Clinical trials can specify certain steps or goals to be achieved. The principal researcher must compile a final technical report for the clinical trial, and where the clinical trial lasts longer than one year, annual technical reports for the Health Authorities must be compiled.

The final technical report must contain, among other things, the following:

- **Summary.** A general overview of the work performed, outcomes, relevant conclusions and possible applications.
- **Preamble.** Theoretical overview of the research, providing general background information and highlighting any relevant problems identified. Hypothesis, justifications and objectives should also be included here.
- **Materials and methods.** A detailed description of the research, including the apparatus and instruments used, together with the validity and quality controls used.
- **Relevant outcomes.** A summary of the actual outcomes of the clinical trial.
- **Analysis and interpretation of the research outcomes.** This should compare them with the studies that support or contradict the research.
- **Conclusions.** Proposals and possible applications.

MARKETING

Authorisation and abridged procedure

8. What is the authorisation process for marketing medicinal products?

Application

COFEPRIS grants marketing authorisations for medicines and other goods.

Authorisation conditions

The LGS and its regulations have been reformed to establish clear rules to improve the safety and efficacy of approved medicines thorough standard clinical trials. A committee studies applications for new drugs (defined as new molecules), which include:

- Medicines to be approved for the first time in Mexico.
- Medicines with a new combination of two compounds that do not exist in the national market.
- Drugs or medications on the market but with a different therapeutic indication.

Amendments were made to the RIS in 2008 to ensure safety and efficacy by eliminating the concept of similar products and including a requirement for an interchangeability test for the approval of generics. Although this reform eradicated the concept of similar products and assures the quality of generic medicines, this modification now contradicts the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) and North America Free Trade Agreement (NAFTA) because it disregards data package exclusivity. Generic applications now benefit indirectly by proving safety and efficacy through interchangeability tests with the product of reference, with no minimum five-year period of no-reliance as required by NAFTA. The recognition of data package exclusivity rights can only currently be achieved through litigation. The author's firm has had two favourable precedents in this regards, although as yet these are not definitive as they are pending appeal.

Other conditions

The holders of the marketing authorisation must comply with good manufacturing practices, stability, pharmacovigilance and labelling standards and all other applicable provisions.

COFEPRIS is empowered to make on-site visits at any time to inspect premises and verify such compliance, and can initiate *ex officio* legal proceedings to prohibit bad practices. Ultimately, these legal proceedings can result in the revocation of the marketing authorisation.

Marketing authorisations must be renewed every five years. Applicants must prove compliance with the above standards before marketing authorisations will be renewed.

Under the Health Law Regulations, the medicines must only be available in authorised drug stores and can only be sold to patients with a physician's prescription (unless they are over-the-counter products).

Key stages and timing

The average time for obtaining a marketing authorisation in Mexico is between 12 and 18 months.

Fee

Fees are approximately:

- New molecules: US$9,000.
- Generics: US$5,000.
- Herbals: US$1,000.

Period of authorisation and renewals

Marketing authorisations must be renewed every five years. As the renewal requirement is a relatively recent change, its application and interpretation has caused some confusion for the pharmaceutical industry.

Post-marketing commitments and pharmacovigilance obligations

Health Law Regulations and the Official Mexican Standard NOM-220-SSA1-2002 for pharmacovigilance establish that the holders of the marketing authorisations must:

- Report to the Health Ministry any adverse event, or suspected adverse reaction, that they are aware of and which may have been caused by their products manufactured or marketed in Mexico.
- Have standard operating procedures:
  - to receive any report of suspected adverse reactions from any possible source;
  - to record, validate and identify any reports of misuse or abuse reported by health professionals or patients;
  - to record and monitor any information related to any product used during lactation and pregnancy;
  - to investigate serious and unexpected cases;
  - to estimate the frequency of suspected adverse reactions and investigate the possible risk factors with intensive pharmacovigilance studies (at the request of the Health Authorities);
  - to ensure the confidentiality of the identity of patients and reporters.

The holders of marketing authorisations must submit reports every six months during the first year after the initial grant of the marketing authorisation. Reports are then submitted annually from the second to the fifth year, and are submitted once every five years once the five-year period has expired.

9. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

Generic companies obtain marketing authorisation for a generic product by providing dissolution profiles or bioavailability studies for the innovator's product. A generic applicant therefore benefits indirectly from the safety and efficacy studies contained in the innovator's dossier. This is a violation of certain international treaties such as NAFTA and TRIPS, which provide a minimum term of five years indirect reliance on data exclusivity to avoid unfair commercial use of the undisclosed information provided by the innovators to the regulatory agencies. The recognition of data package exclusivity rights can only currently be achieved through litigation. The author's firm has had two favourable precedents in this regards, although as yet these are not definitive as they are pending appeal.

10. Are foreign marketing authorisations recognised in your jurisdiction?

In general, Mexico does not recognise foreign marketing authorisations. However, some licences and authorisations can be recognised or granted in Mexico based on co-operation agreements signed by Mexico and other countries.

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

COFEPRIS can request reports from, and make on-site inspection visits to, marketing authorisation holders to both:

- Verify that their products meet the approved specifications and do not represent a health risk.
- Ensure that good manufacturing practices, stability, pharmacovigilance and labelling standards are being complied with.

Imposing penalties

COFEPRIS can impose strong administrative and criminal sanctions for breaches of marketing authorisations.

Parallel imports

12. Are parallel imports of medicinal products into your jurisdiction allowed?

Parallel imports are allowed in Mexico for trade marks where both the:

- Product was legally introduced in the country of origin.
- Trade mark is owned by the same company or a related company in Mexico.

The Intellectual Property Law (IPL) does not specifically address patents. However, it is likely that the principle of exhaustion of rights also applies to patents.

Restrictions

13. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Government officers must not request, accept or receive any gifts or donations from persons whose commercial or industrial activities they are directly linked to, or that they regulate or supervise (*Article 8, Federal Law of Responsibilities for Government Officers*).

Doctors working for the IMSS or ISSSTE are considered to be government officers and are therefore not allowed to receive gifts or donations from pharmaceutical companies when on duty and working in the name or facilities of IMSS or ISSSTE.

The LGS and its regulations do not address doctors in private practice, although they specify that private doctors must act according to professional ethics.

Companies must not provide doctors with goods or incentives of any kind to use, prescribe, purchase or recommend a medicinal product or to influence the result of a clinical trial (*Article 4.9.1, Code of Good Practices of Advertising of the National Chamber of the Pharmaceutical Industry* (CANIFARMA)). The corresponding sanctions range from a warning to a fine.

Similarly, CANIFARMA's Code of Ethics indicates, in general terms, that companies should act responsibly in relation to sponsorships and donations.

Mexico does not currently have any anti-bribery laws to limit these practices, and there is no domestic legislation to regulate these cases beyond Mexico's jurisdiction. However, Mexico has ratified certain international treaties which do regulate, and in some cases prohibit, these practices.

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

Electronic advertisement falls under the general rules for advertising in Article 2 of the Regulation of the General Law of Health regarding Advertising (*Reglamento de la Ley General de Salud en Materia de Publicidad*) (RGLHRA). There are no specific rules on internet advertisement.

ADVERTISING

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

Advertising of medicinal products in Mexico is governed by the RGLHRA and opinions issued by the Advertising Council. COFEPRIS enforces the provisions on advertising.

The IPL and the Federal Law for Protection of Consumers both have provisions on advertising, and the National Chamber of the Pharmaceutical Industry has a Code of Ethics that includes provisions on advertising. Although these provisions are not mandatory, failure to comply can result in a suspension of rights as a member of the Chamber or exclusion from it.

Restrictions

Only non-prescription medicines can be advertised to the general public. It is not possible to advertise prescription medicines to the general public (*Article 310, LGS*). Any visual or audio advertisement for non-prescription medicines must bear the message "Consult your physician" and must mention any required precautions when the use of the medicine represents any danger in the case of an existing pathology (*Article 43, RGLHRA*).

Prescription medicines can be advertised to health professionals. However, advertisement directed to health professionals can only be published in specialised media and it must be based on medical prescription information (*Article 42, RGLHRA*).

Internet advertising

Electronic advertisement falls under the general rules for advertising in Article 2 of the RGLHRA and there are no specific rules for internet advertisement. However, the health authorities monitor internet advertisements less stringently than television or radio advertisements and there are few cases of actions by COFEPRIS related to internet advertisements.

PACKAGING AND LABELLING

16. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

Packaging and labelling of medicinal products is regulated by the:

- LGS.
- RIS.
- NOM 072-SSA1-1993 relating to the labelling of medicinal products.

COFEPRIS is responsible for enforcing the provisions concerning the packaging and labelling of medicinal products.

Information requirements

The labelling of medicinal products must include the following information (*NOM 072-SSA1-1993 and RIS*):

- Distinctive brand name.
- Generic name.
- Pharmaceutical form.
- Drug concentration.
- Formulation.
- Formula description.
- Dose.
- Mode of administration.
- Conservation and storage information.
- Precaution and warning legends, including risks in case of pregnancy.
- Sanitary registration code.
- Batch number.
- Expiration date.
- Manufacturer's and, if applicable, distributor's information, including address.
- Content.
- Maximum price to the public.
- Active ingredients description.
- In cases of drugs with biological origin, the specifications of the live organism that was used for the preparation of the medicinal product and the name of the disease for which it is indicated, according to the revised international nomenclature.

Other conditions

The information can be stated in another language, although the information must also be stated in Spanish in the same font and at least in the same size.

TRADITIONAL MEDICINES

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

Traditional herbal medicinal products can contain excipients and additives besides vegetable materials (*Health Products Regulation*).

Traditional herbal medicinal products must not:

- Be isolated or chemically defined active ingredients.
- Be injectable.
- Include psychotropic or narcotic substances.
- Be mixed with conventional medicines or other substances that represent a health risk.

Traditional herbal medicinal products can be advertised to the general public. Any visual or audio advertisement must bear the message "Consult your physician" (*Article 310, LGS*).

Advertisements must limit themselves to indicating the general characteristics of the product, its therapeutic properties and use.

PATENTS

18. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Patent applications are regulated by the IPL and its regulations. Patentable inventions must (*Article 16, IPL*):

- Be novel.
- Result from an inventive step.
- Be industrially applicable.

Scope of protection

Products and processes can be the subject of patent protection under the IPL.

In 1991 the IPL was reformed, removing the prohibition on patenting medicinal products and pharma-chemicals. The Mexican Institute of Industrial Property (IMPI) now grants patents protecting the compounds, formulations, uses and manufacturing processes of medicines.

Article 19 of the IPL excludes medical procedures from being the subject matter of an invention. However, a patent can be obtained for a therapeutic method by drafting the claims in the Swiss-style format, that is, claiming the medical use of the compound for the treatment of a specified illness.

19. How is a patent obtained?

Application and guidance

Applications must be made to the IMPI. The government fees are:

- Filing a patent application: about US$720.
- Issuing the patent title: about US$300.
- Annual payments:
  - years one to five: US$100;
  - years six to ten: US$120;
  - years 11 to 20: US$150.

Process and timing

The average time for obtaining a Mexican patent varies depending on the field of technology. Generally, it takes from four to six years to obtain a patent.

A patent is obtained by filing a patent application with the IMPI.

The key stages are:

- Filing a patent application with the IMPI. The patent application consists of a narrative statement about the invention that includes:
  - a description of the invention that is sufficiently clear and complete to allow it to be fully understood and to guide any person knowledgeable in the invention's field;
  - the best method known by the applicant of putting the invention into practice;
  - drawings required for an understanding of the description, when necessary;
  - a claims chapter, which must be clear and concise, and must describe the invention's concept without overlapping with the description.

  If the application is filed in English, the corresponding Spanish translation must be filed within two months commencing from the filing date.

  A filing date is received by filling a request form, delivering the narrative statement and submitting the application to the IMPI at its central or regional offices.
- The certified copy of the priority right document (only applicable to Paris Convention for the Protection of Industrial Applications 1976 (Paris Convention)) must be filed within three months from the filing date.
- The IMPI conducts a formal examination of the documentation and may order clarifications or further details, or that omissions be remedied. If so, an official communication requests the outstanding documents (that is, a power of attorney and an assignment of rights). This communication is usually issued four to six months after filing.

  The IMPI grants the applicant a term of two months, and two additional months, on payment of extra fees, to comply with these requirements. If the applicant fails to comply with these requirements in the four-month total term, the application is deemed to be abandoned.
- After all the formal documents have been filed an official communication is issued that all the formal requirements are complied with and taking note of the priority claimed, when applicable.
- The abstract is published in the *Official Gazette*. This step normally occurs 18 months after the filing of the priority claim, or if no priority is claimed, 18 months from the filing date.
- Examination on the merits of the invention begins automatically after the corresponding fees are paid concurrently with filing the application.
- An official action is issued about three years after the filing date either requesting amendments to the claims (due to disapproval or clarification regarding novelty, and so on), or granting the protection sought and requesting payment of the final IMPI fees together with the payment of the first five annuities.
- Maintenance fees are due every five years until the life of the patent is terminated.

Deposit system

The IMPI operates a deposit system. The IMPI has to review the patent application as it is submitted. If there is information missing from the application, the IMPI should request that the applicant complete that missing information.

20. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

The term of a Mexican patent is 20 years from the effective filing date of the patent application. For Paris Convention and non-Paris Convention applications, the effective filing date is the filing date in Mexico. For Patent Cooperation Treaty 1970 applications, the effective filing date is the date of filing of the international patent application.

The patent cannot be renewed.

In general, Mexican law does not allow patent term extensions. However, there are two specific situations where there may be an exception:

- In 1991 the IPL was amended to allow patenting of pharmaceutical compounds. These patents were subject to a pipeline regime in which the life term of the Mexican patent was tied to the life term of a patent application or patent granted abroad. This caused several patent terms to be modified either directly by IMPI or through litigation, when proven that the patent application had a different life term. All of these patents will expire no later than June 2012.
- NAFTA (*Article 1709, section 12*) establishes the possibility of patent correction cases due to delay in regulatory proceedings. However, Mexican domestic law has not adopted this provision and therefore, the direct enforcement of NAFTA would be very difficult to obtain in Mexico.

Extending protection

There are no provisions for exclusivity term extensions or supplementary protection certificates in domestic law.

In theory, the life term of a patent could be extended under certain international treaties (for example, NAFTA) where the Health Authority has delayed the process to obtain a marketing authorisation for a patented product. However, in practice no-one has yet attempted to do this. We would suggest that anyone seeking to extend the life term of a patent on these grounds would need to argue that the international law has supremacy over Mexico's domestic legislation in order to succeed in their application.

Further, and arguably in conflict with international law (which contains provisions concerning industrial secrets and the protection of data package exclusivity rights (DPE)), Mexico does not have any domestic legislation which expressly establishes and protects DPE.

Under NAFTA, any undisclosed information submitted for the purposes of obtaining a marketing authorisation for products using new chemical compounds should be protected from being copied by third parties for a minimum of five years. The five-year period runs from the date that the marketing authorisation is granted (*Article 1711, NAFTA*). However, in Mexico it is possible for an applicant for a marketing authorisation for a generic medicine to simply supply the dissolution profiles or bioavailability studies of the innovator product (instead of having to supply their own profiles and studies proving the safety and efficacy of their products). We would argue that this is in direct conflict with the international law, since effectively it provides an implicit authorisation that the innovator product's safety and efficacy studies can be relied upon by third parties (instead of being protected, as they are under the international legislation).

21. How can a patent be revoked?

The validity of a patent can be challenged through a nullity action before the IMPI. A patent can be established as invalid by proving one of the following:

- The patent covers subject matter that cannot be regarded as an invention, product or process.
- The subject matter qualifies as an invention but the patent does not meet one or more of the patentability standards or conditions (novelty, inventive activity or step and industrial application).
- The patent was granted in contravention of the law and does not comply with formal or technical legal provisions.
- The patent was granted due to an error or serious oversight, or was granted to someone not entitled to obtain it.

In the first three situations the nullity action can be exercised at any time. In the fourth situation the nullity action must be exercised within five years from the date on which the publication of the patent in the *Official Gazette* occurred or when registration becomes effective.

22. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

The IPL grants patentees the right to the exclusive exploitation of the patented invention and to exclude others from making, using, offering for sale or importing the covered invention. In a patent infringement action, the claimant must prove:

- Ownership or recorded licence over a granted, valid and fully in force patent. Generally, a certified copy of the "file wrapper" of the patent prosecution is enough to prove these requirements. Validity of the patent can be challenged by the defendant.
- The production, offering to sell or importing of the patented invention. A manufacturer can infringe directly, while infringement by sellers requires prior notice of the infringement. When a claimant claims infringement of a patented process, the defendant has the burden of proving the use of a process other than the patented process. There are no grounds in the IPL to apply the contributory infringement doctrine.
- Use of the patented invention. The IPL only recognises literal infringement and there is no doctrine of equivalence. The claimant must prove that the wording of the patent's claim or claims cover the alleged infringing product or process. First, the claimant must define the scope of the approved claims. The IPL provides that the span of the claims is determined by the wording of the claims, aided by the description and drawings. The interpretation of the claims and the use of the patented invention on the infringing product or process are technical issues. Therefore, infringement actions may require expert evidence even though the technical department of the Patent Office will provide a report to its legal team.
- Non-authorised use. The burden of proving authorisation is on the defendant. The doctrine of implied licence has never been tested before the Mexican courts.

Claim and remedies

Claim. The IPL grants patentees the right to the exclusive exploitation of the patented invention. Therefore, a patent grants the right to exclude others from making, using, offering for sale or importing the patented invention. In a patent infringement action, the claimant must prove the following:

- Ownership or recorded licence over a granted, valid and fully in force patent. Generally, a certified copy of the "file wrapper" of the patent prosecution is enough to prove these requirements. Validity of the patent can be challenged by the defendant.
- That someone is using, making, offering to sell or importing the patented invention. The IPL establishes direct infringement over the manufacturer. Infringement against sellers requires evidence of prior notice of the alleged infringement. When a claimant claims infringement of a patented process, the defendant has the burden of proving the use of a different process other than the patented process. There are no grounds in the IPL to apply the contributory infringement doctrine.
- Use of the patented invention. Under the IPL, only literal infringement is recognised. No doctrine of equivalence applies.

The claimant must define the scope of the approved claims. The IPL provides that the breadth of the claims is determined by the wording, aided by the description and drawings.

Interpretation of the claims and the use of the patented invention in the accused product or process are technical issues. Therefore, infringement actions require additional proof from experts even though the corresponding Technical Centre of the IMPI may provide a technical report.

The burden of proving authorisation is on the defendant. The doctrine of implied licence has never been tested before the Mexican courts.

Proving patent infringement in Mexico is a difficult task, since the jurisdiction follows a strict civil law system which has formalistic rules for both evidence and proceedings.

The patent infringement claim must be submitted before the IMPI. The claim is served on the alleged infringer, who then has ten working days to respond and, if applicable, bring a counterclaim. That response is then served on the claimant for the claimant to refute it. All the evidence is analysed, and finally a decision is issued. That decision can be challenged before the Federal Courts.

The IMPI is an administrative authority. There is no judge or jury participation in patent infringement actions.

Remedies. The IPL provides that preliminary injunctions can be requested, allowing the IMPI to take certain measures against defendants during the process of investigating the infringement. Preliminary injunctions established by the various sections of Article 199 *bis* include:

- Ordering the recall or preventing the circulation of the infringing merchandise.
- Ordering the following to be withdrawn from circulation:
  - illegally manufactured or used articles;
  - articles, packaging, wrapping, stationery, advertising material, and other similar items that infringe any of the rights protected by law;
  - advertisements, signs, posters, and other similar articles that infringe any of the rights protected by law; and
  - utensils or instruments destined for or used in the manufacture, production or obtainment of any of the articles mentioned above.
- Immediately prohibiting the marketing or use of the products with which any rights protected by the law are violated.
- Ordering the attachment of the products under Articles 211 to 212 *bis* (2) of the IPL.
- Ordering the alleged transgressor or third parties to suspend or cease all acts that constitute a violation of the provisions of the law.
- Ordering a suspension of service or the closure of the establishment when the measures indicated above are insufficient to prevent or avoid the violation of rights protected by the law.

If the product or service is in trade, the merchants or service providers must refrain from selling the product or rendering the service from the notification date of the resolution.

The same obligation is imposed on the producers, manufacturers, importers and their distributors, who must take responsibility for the immediate recall of the products that are found in trade.

Administrative infringements are punishable with sanctions ranging from a fine of up to 20,000 times the minimum wage (approximately US$80,000) to a definitive closure of the establishment (*Article 214, IPL*). Repeated infringement activity is also considered a criminal offence (*Article 223, IPL*).

Once an infringement has been declared and cannot be appealed, the claimant can pursue an additional civil action for damages and lost profit.

Damages and lost profit start accruing from the date on which the existence of an infringement can be proven. In this regard, Article 221 *bis* of the IPL provides that "the repair of material damages or the indemnification of damages and lost profit resulting from a violation of the rights conferred by this law will never be lower than 40% of the sale price to the public of each product or the rendering of services that implies a violation of any one or more of the industrial property rights regulated by this law".

The civil courts follow a specific scheme covering the costs that can be claimed for reasonable attorneys' fees, regardless of whether this table reflects the actual fees charged.

23. Are there non-patent barriers to competition to protect medicinal products?

The data package exclusivity period that is provided in international law but not in domestic law is currently being tested before the Federal Courts.

The General Health Law and the Mexican Pharmacopeia have established a definition for orphan drugs, but as yet they do not have data package exclusivity. Given this situation, the recognition of data package exclusivity regarding orphan drugs could only be achieved through litigation.

TRADE MARKS

24. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

All visible signs can be protected as a trade mark if they are sufficiently distinctive and able to identify the products or services to which they apply or are intended to apply against others in the same class (*Article 89, IPL*). Trade marks in Mexico are regulated under the IPL.

Scope of protection

Brands for medicinal products can be registered as trade marks. Three-dimensional forms can be protected as trade marks, as these are visible signs, if they comply with the principle of distinctiveness. However, the IPL establishes the following limitations for three-dimensional marks:

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

The IMPI holds that the slightest indication of a product shape can trigger an objection or rejection based on the mark being merely descriptive and not sufficiently descriptive. This is problematic for pharmaceutical products where the trade mark application purports to protect the shape, combination of colours and/or designs in the pills and tablets. Fortunately, case law shows that in reviewing the IMPI's rejections, the Mexican courts have taken a trade mark fashion interpretation of prohibitions that were focused on distinctive and non-functional elements, and some of the rejections by the IMPI have been reversed.

New marketing authorisations granted by COFERPRIS for two or more provisions that are orthographic or phonetically similar must differ at least by three letters of each word (*Article 23, Regulation of the LGS*). This is known as the three-letter rule.

The IMPI studies and grants trade mark registrations, but also reviews the first stage of any administrative litigation where the IMPI has been reluctant to apply the three-letter rule. The IMPI's interpretation of the IPL and the Regulation of the LGS is controversial and may lead to undesirable scenarios, such as contrary decisions by the IMPI and COFERPRIS on the likelihood of confusion over the same trade mark. However, some courts have determined that the three-letter rule must be taken into consideration by the IMPI when deciding the likelihood of confusion between trade mark registrations applied for by pharmaceutical products. As there is legal uncertainty in this area, an analysis is required on a case-by-case basis.

25. How is a trade mark registered?

Application and guidance

The application is made to the IMPI. The government fees for filing a trade mark application are around US$25. If objections are faced, further fees may be accrued in the region of US$125.

Process and timing

If the trade mark registration for a word mark does not face any objection as to its inherent registrability and there is no known similar or identical prior registered mark, completing registration can take three to four months. For a design trade mark, it can take at least six months because searches for prior registrations regarding designs are mainly conducted manually by the IMPI.

All new trade mark applications are subject to a dual examination by the IMPI. The first formal examination is focused on checking compliance with all formal legal requirements (the official application form must be duly completed and the government fees paid, and so on). After this the second examination takes place. The inherent registrability (without evidence of use) is determined at this second stage, that is, whether the proposed trade mark has any negative linguistic (or other) connotations that would make it unacceptable in the local language, and so on. The examiners then conduct an online search of the IMPI's database to determine whether there is already a trade mark (on record or at the registration stage) that could be considered similar or confusingly similar to the proposed mark. If a similar trade mark is revealed in the search, it is analysed to determine whether the confusion between them is triggered by their graphic, phonetic or conceptual aspects, considering the similarities between the products or services of interest.

If the examiners find that a prior mark is a barrier to registration of the proposed mark or that the application does not comply with all the formal requirements, an official action is issued detailing these reasons and granting the trade mark applicant a two-month term (automatically extendable for a further two months) to comply with the formal requirements or to provide legal arguments. The IMPI then grants or refuses the registration. On the applicant's request, the IMPI holds the trade mark application in the event that a legal action against the prior registrations takes place.

There is no opposition system in Mexico and currently the IMPI's approach is to not recognise consent letters or co-existence agreements for identical or confusingly similar trade marks owned by different parties.

26. How long does trade mark protection typically last?

Duration and renewal

Trade mark registrations are valid for ten years from the filing date and can be renewed for any number of further ten-year periods.

Renewal of trade mark registration can be requested by the holder from six months before its renewal date. However, the IMPI will accept and process renewal petitions filed within a six-month grace period after the renewal date, with the payment of an additional government fee.

If the registration is not used and not contested by any third party, it remains in full force until its renewal.

A trade mark registration can only be renewed if the interested party presents proof of payment of the fee and presents an affidavit to the effect that it uses the trade mark on at least one of the products or services and that it has not interrupted this use for at least three consecutive years, otherwise the renewal is not allowed and the registration lapses.

The government fees for renewing a trade mark are around US$269. The IMPI charges US$7 extra for each month of late filing after the renewal date during the grace period.

The estimated time frame for a trade mark renewal is approximately two months from application.

Extending protection

As the term of a trade mark registration can be indefinitely renewed for ten-year periods, the IPL does not establish other way to extend the term of registrations.

27. How can a trade mark be revoked?

If a trade mark is not used for three consecutive years in relation to the goods or services for which it is registered, the registration is subject to cancellation for non-use, unless either (*Articles 130 and 152(II), IPL*):

- A duly licensed holder or user has used the mark for three consecutive years immediately before the filing date of the cancellation action.
- There are legitimate reasons for the non-use that are beyond the control of the trade mark owner (for example, import restrictions or other government requirements).

Trade marks can be cancelled if (*Article 151, IPL*):

- The registration was granted in contravention of the provisions of this law or of the law that was in effect at the time of its registration, although the nullity action cannot be based on a challenge to the applicant's legal representation. An action on these grounds can be made at any time.
- The trade mark is identical or confusingly similar to another that has been used in the country or abroad before the application for the registered trade mark and is applied to the same or similar products or services. An action on these grounds must be made within three years of the trade mark's registration.
- The registration was granted on the basis of false information in the application. An action on these grounds must be made within five years of the trade mark's registration.
- The registration was granted in error. An action on these grounds must be made within five years of the trade mark's registration.
- The agent, representative, user or distributor of a trade mark registered abroad requests and obtains registration in his name of the trade mark or another confusingly similar one, without the express consent of the holder of the foreign trade mark. In this situation the registration is deemed to have been obtained in bad faith. An action on these grounds can be made at any time.

28. How is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

A trade mark registration can be enforced against alleged infringers in two different venues:

- The IMPI, if the infringer is using a confusingly similar trade mark distinguishing identical or similar goods or services to the one covered by registration. The IMPI can impose a fine and order an immediate halt to the infringing activities. A civil action to claim damages before a civil court is possible once the IMPI's resolution declaring the infringement of a trade mark registration is final and beyond the possibility of appeal. When an infringement case has come to a conclusion, a successful claimant is entitled to claim no less than 40% of the entire sales of the infringing product at the sale price before a civil court.
- The Federal Prosecutor's Office, if the infringer is using a trade mark identical to the one registered to distinguish the same goods or services (falsification or counterfeiting). There are no other criminal provisions on trade mark enforcement.

Claim and remedies

Claim. In terms of trade mark infringement, the claimant has the burden of proving the use of a confusingly similar trade mark by a third party without authorisation. The issue of confusing similarity between the registered trade mark and the one in use by the infringer is a matter of law that must be decided by the IMPI.

Regarding pharmaceutical products, Article 23 of the Health Law Regulations establishes that when similarity is found between a drug trade mark and an earlier drug trade mark, at least three letters should differ before the regulatory agency can authorise the marketing of that drug with that trade mark.

This provision is known as the three-letter rule. Its rationale is to avoid granting marketing authorisation to a junior trade mark similar to that of a prior marketing authorisation.

The three-letter rule is not currently applied by the Mexican Trademark Office when they grant trade mark registrations or handle invalidity or infringement actions at first stage, and the Federal Courts currently have divided criteria on the application of the rule.

A claimant can bring an action for unfair competition, where it must prove actual confusion among consumers. In this case, the confusion is not a matter of law but a matter of fact, and the claimant has the burden of proving that the use of the trade mark by the infringer makes some form of false representation that tends to cause consumers to believe that the defendant's goods or services come from the claimant.

To prove the infringement, the claimant can file any kind of evidence available except confessional and testimonial evidence. The most commonly used evidence to help prove trade mark infringement is an inspection of the infringer's premises. The inspection is conducted by an IMPI inspector and it usually takes place either:

- At the moment notice of the claim is served.
- When an order imposing a preliminary injunction is served on the defendant.

A kind of discovery is available for the claimant.

The prosecution of an infringement claim before the IMPI is simple and begins with the filing of a formal written claim. Once the IMPI admits the claim, this is served on the alleged infringer, who then has ten working days to respond and, if applicable, bring a counterclaim. That response is served on the claimant for the claimant to refute it, and all evidence is analysed. Finally, a decision is issued. This decision can be challenged before the Federal Courts.

Remedies. The IPL provides that preliminary injunctions can be requested, either before the infringement claim is filed or during the investigation into the alleged infringement.

For more information on preliminary injunctions, sanctions and civil actions for damages and lost profits, see *Question 22*.

Regarding counterfeiting, there is a criminal enforcement mechanism where the infringer uses a mark identical to a registered trade mark for identical goods or services, where the trade mark owner can enforce its rights by filing a criminal action before the Attorney General's Office.

To commence a criminal action, the injured party must first file a complaint. Upon receiving the complaint, the Attorney General's Office will launch a preliminary inquiry to determine whether a crime has been committed and, if so, who is responsible.

The District Attorney gathers all evidence required to reach a conclusion, with the assistance of the injured party. If the results of the inquiry reveal that a crime has occurred, the District Attorney submits the matter to a federal district judge who, following precise constitutional and legal procedures, decides whether to issue an apprehension order against those allegedly responsible for the crime. Once the authorities (the federal police) have complied with the apprehension order, the federal judge will issue a "formal prison" order, which serves as the starting point of the corresponding trial. The parties to the trial are the Attorney General's Office and the defendants.

The defendants can appeal against the two court orders. The unsuccessful party to the trial can appeal the decision before a unitary court, whose decision is binding.

Criminal penalties range from between two and ten years' imprisonment, to approximately US$100,000 in fines. Both imprisonment and fines can be imposed simultaneously.

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

Recording a patent or a trade mark licence agreement is not mandatory and the agreement is enforceable between the parties regardless of whether or not it is recorded. However, to be effective against any third party, and to ensure the title holder has the use of the trade mark or patent, the licence agreement must be recorded with the IMPI (*IPL*).

COFEPRIS can request applicants to prove whether they are the owner or licensees of the patents in the *Linkage Gazette*. A similar situation can occur for trade marks under the three-letter rule (*see Question 24*).

The government fees to record a patent licence agreement before the IMPI are around US$316. The government fees to record a trade mark licence agreement before the IMPI are around US$39. Completing the licence agreement can take two to three months.

There is no requirement for a remittance of royalties under a patent or trade mark licence agreement to a foreign licensor to be approved by any government or regulatory body.

THE REGULATORY AUTHORITY

Federal Commission for Protection against Sanitary Risk (*Sitio Oficial de la Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS)

W *www.cofepris.gob.mx*

Main areas of responsibility. Main areas of responsibility. Part of the Ministry of Health, COFEPRIS is responsible for enforcing the regulatory framework in relation to medicines.

Patent and trade mark conventions

30. Is your jurisdiction party to international conventions on patent and trade mark protection?

Mexico is a signatory to the following international trade mark treaties:

- NAFTA (Sixth Part, Chapter XVII- Intellectual Property).
- TRIPS.
- Paris Convention.
- The Mexico-France Convention for the Mutual Protection of Industrial Property (1900).
- The Mexico-EU Free Trade Agreement (Chapter VI- Intellectual Property).
- The Mexico-Uruguay Free Trade Agreement (Chapter XV- Intellectual Property).
- The Mexico-Salvador-Guatemala-Honduras Free Trade Agreement (Chapter XVI- Intellectual Property).
- The Mexico-Chile Free Trade Agreement (Chapter XV- Intellectual Property).
- The Mexico-Nicaragua Free Trade Agreement (Chapter XVIII- Intellectual Property).
- The Mexico-Colombia-Venezuela Free Trade Agreement (Chapter XVIII- Intellectual Property).
- The Mexico-Costa Rica Free Trade Agreement (Chapter XIV- Intellectual Property).
- Patent Cooperation Treaty 1970.

PRODUCT LIABILITY

31. Outline the scope of medicinal product liability law.

Legal provisions

In general terms, liability arises from provisions in federal or local Civil Codes in Mexico. Liability can also arise from statutory terms.

Substantive test

Liability claims are mainly regulated by statutes and not by court precedents. Therefore, there is no clear substantive test.

Liability

Individuals who are guilty of the manufacturing, distributing, storage and transportation in the case of falsification, alteration and contamination of products can be liable.

32. How can a product liability claim be brought?

Limitation periods

Depending on the conduct and cause of action, the limitation periods are one to nine years for some criminal sanctions and two to ten years for civil actions.

Class actions

Class actions are not allowed under Mexican Law. However, there is a current proposal to pass a law to allow for class actions. Currently, the *accion popular* is available in which any individual with or without proper legal standing can file a complaint before COFEPRIS, arguing and proving that there are certain health risks in a product in the market. However, the claimant's procedural rights are very limited, and these actions are intended to cease a health risk and not to obtain compensation.

Foreign claimants

Under the Mexican Constitution, foreign nationals and nationals must receive equal treatment before the IMPI and the Mexican courts.

33. What defences are available to product liability claims?

Equitable defences are available.

34. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

Preliminary injunctions can be ordered to stop the commercialisation and distribution of a product. Monetary compensation is the most common remedy but equitable remedies are also available. Punitive damages are not subject to regulation and there are no public precedents to make estimations in this regard.

REFORM

35. Are there proposals for reform and when are they likely to come into force?

In response to the fact that data package exclusivity periods were not expressly included in the recent amendments to the LGS (as was expected, to bring domestic law in line with the international treaties), a proposed amendment to the law was published in the *Gazette of the Congress* in February 2011. The proposed amendment concerns Article 376 of the LGS, and intends to create a five-year data package exclusivity period for innovator products. This will prevent third parties from benefiting from using the innovator product's trial data in their own marketing authorisation process (unless they have express permission to do so). The following points concerning the proposed amendment should be considered:

- The word "interchangeable" contained in Article 376 should be removed, since there is no longer any distinction made between "generics" and "interchangeable generics".
- The proposal does not make specific distinctions between the protection of new chemical entities, formulations and new indications.
- The proposal limits the scope of data package exclusivity to five years, while NAFTA establishes the five-year period as a minimum.
- The proposal seems to be limited to allopathic medicines of a chemical nature, as there is no specific mention of biological drugs. In other jurisdictions, biological drugs actually obtain a longer protection period.

This proposal would put domestic legislation in line with the international law and is to be welcomed. It will be interesting to see if the proposal becomes law before the next Presidential elections in Mexico.

**The contributor would like to thank Erwin Cruz for his valuable contribution to the compilation of this chapter.*

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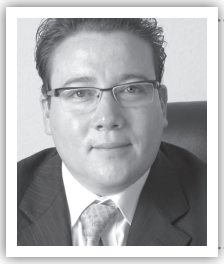

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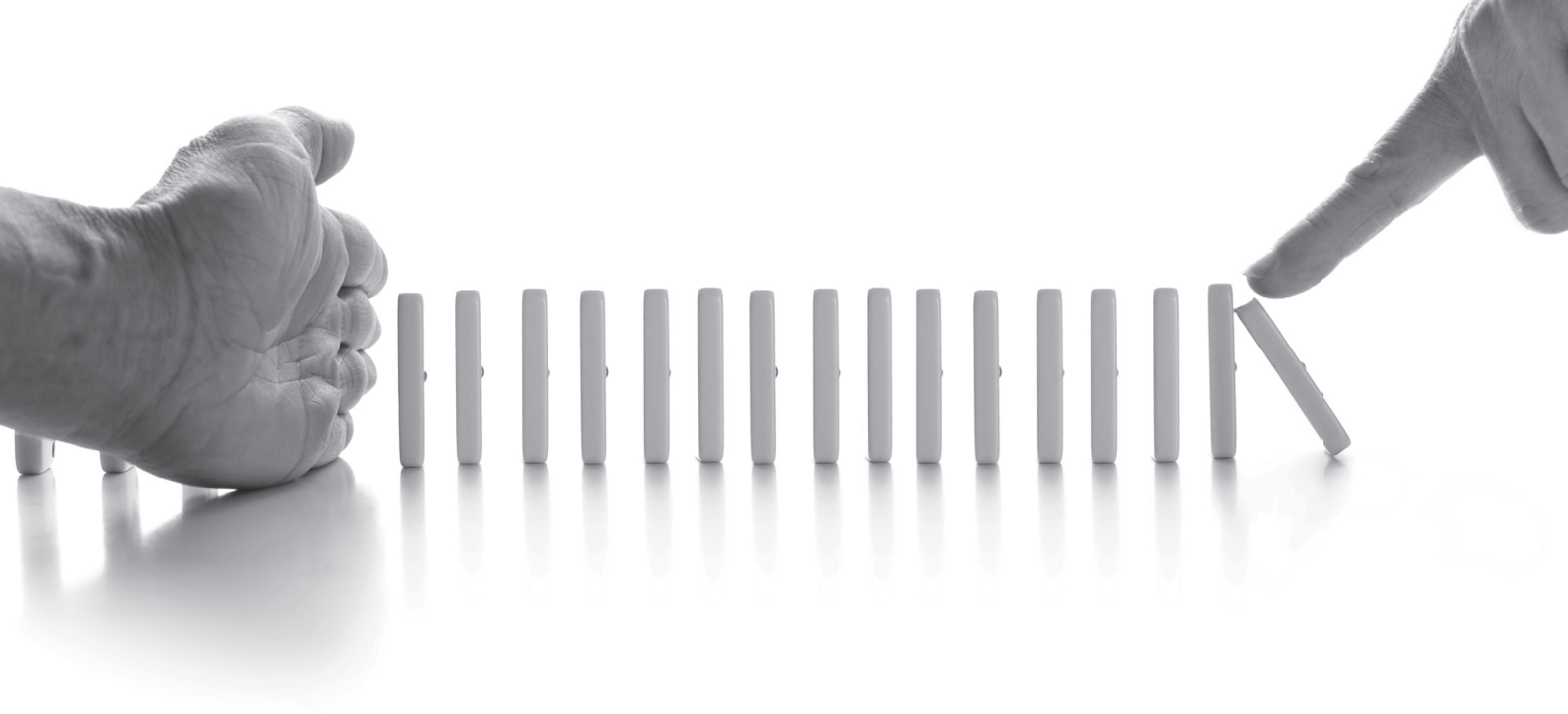
Areas of practice. IP; litigation and regulatory issues.

Recent transactions

- Participated in cases against the unconstitutionality and inefficiency of certain amendments to the Federal Law of Administrative Proceedings in Mexico, which have affected the venues for challenging resolutions by the Mexican Institute of Industrial Property.
- Sponsor of a proposal to modify the litigation system of industrial property, limiting the Mexican Institute of Industrial Property to an exclusive registration authority, transferring jurisdiction to Civil Courts in infringement cases, and cases related to the annulment of trade mark registrations or patents to administrative courts.



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