

PATENTS

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The International Comparative Legal Guide to:

Patents 2017

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A practical cross-border insight into patents law

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Mexico

Alejandro Luna



Sergio L. Olivares, Jr.



OLIVARES

1 Patent Enforcement

1.1 Before what tribunals can a patent be enforced against an infringer? Is there a choice between tribunals and what would influence a claimant's choice?

In Mexico, the problem of selecting the competent judge or choosing jurisdiction is minimal. Indeed, the only venue to enforce a patent is through administrative proceedings (infringement action) before the Mexican Patent Office (IMPI), which is not a Court of Law, but a Federal administrative entity. IP enforcement is Federal law; no state law is available. However, the decisions of this agency on patent infringement cases can be appealed by any one of the intervening parties, thus bringing the matter up before a single specialised IP Court. The decision issued by the IP Specialised Court could be appealed before 20 Federal Circuit Courts at Mexico City; however, the case is turned randomly by a computer system. By territorial jurisdiction, IP matters are mainly decided in Mexico City.

1.2 What has to be done to commence proceedings, what court fees have to be paid and how long does it generally take for proceedings to reach trial from commencement?

Traditionally, the Mexican Courts do not address the existence of patent infringement; as in accordance with the Mexican Industrial Property Law (LIP), such cases must be filed and prosecuted with the IMPI. Therefore, arguments should be filed in writing and following applicable procedural rules to commence the procedure.

Government fees to commence a proceeding (patent infringement or invalidity) before the IMPI are around USD 73.

The proceeding before the IMPI usually lasts 12 to 18 months. This is the first stage; at least two additional stages are available.

1.3 Can a party be compelled to disclose relevant documents or materials to its adversary either before or after commencing proceedings, and if so, how?

The IMPI may obtain all the evidence deemed as necessary for the verification of facts that may constitute a violation of one or more of the rights protected by this Act or the administrative declaration procedures.

When the owner concerned or the alleged infringer has submitted sufficient evidence to reasonably have access to support his claims,

and has specified evidence relevant to the substantiation of its claims that is under the control of the opposing party, the IMPI may order the presentation of such evidence before commencing proceedings and, where applicable, this authority should ensure the conditions for the protection of confidential information.

1.4 What are the steps each party must take pre-trial? Is any technical evidence produced, and if so, how?

All pieces of evidence should be filed or announced with the original infringement claim or with the invalidity action before the IMPI. The applicable Regulations do not contemplate a pre-trial stage; therefore, there is no evidence produced in such a stage, but its preparation may be necessary.

1.5 How are arguments and evidence presented at the trial? Can a party change its pleaded arguments before and/or at trial?

Arguments should be filed in writing, following applicable procedural rules. All arguments and evidence must be filed along with the initial brief requesting the infringement action, with an exception being provided for supervening evidence. The general rule is that parties cannot change their pleaded arguments, unless there are supervening or unknown facts.

1.6 How long does the trial generally last and how long is it before a judgment is made available?

The initial stage before the IMPI of a patent infringement action usually takes two years. Once the IMPI issues a decision, the two further stages of appeals before Courts, lasting no fewer than three more years, are expected.

1.7 Are there specialist judges or hearing officers, and if so, do they have a technical background?

The IMPI is considered the only authority to solve patent enforcement proceedings in the first instance.

In January 2009, a specialised IP Division at the Federal Court of Tax and Administrative Affairs (FCTAA) began operating. This Division has jurisdiction to review all cases based on the LIP, the Federal Copyright Act, the Federal Law of Plant Varieties and other IP-related provisions. The creation of this Division should help improve, in general terms, the applicable criteria for IP cases, but the three Magistrates forming this tribunal have no technical

background. The last appeal stage is formed by Federal Circuit Magistrates, although they are highly capable in legal issues and they do not therefore need to have IP or technical backgrounds.

1.8 What interest must a party have to bring (i) infringement, (ii) revocation, and (iii) declaratory proceedings?

- I) Any patentee or licensee (unless expressly forbidden from doing so) has the right to prosecute a suit against a third party infringing his or her rights. A distributor may not bring a suit for infringement.
- II) An accused infringer may counterclaim patent invalidity under formal or technical considerations upon receiving the infringement suit before the IMPI, but it is not possible to request an additional judicial ruling or declaration.
- III) Cease and desist letters provide the required legal standing to initiate invalidity actions. If pertaining to a specific industrial or commercial activity (i.e. the pharmaceutical industry) to provide legal standing, this is subject to debate and the Courts are divided.
- IV) Amendments to the Patent law allow anyone to request the IMPI to initiate officiously the cancellation proceeding against patents.
- V) Simple legal standing, namely, the mere business or commercial activity to challenge the validity of patent, is under assessment before the Courts.

1.9 If declarations are available, can they address (i) non-infringement, and/or (ii) claim coverage over a technical standard or hypothetical activity?

No declarations are available.

1.10 Can a party be liable for infringement as a secondary (as opposed to primary) infringer? Can a party infringe by supplying part of, but not all of, the infringing product or process?

There is no specific provision in the IP law relating to the doctrine of contributory infringement but there is some room to argue in favour of this doctrine; however, it has not been tested before the IMPI or the Courts. Actions may be brought against distributors of an infringing product, and provisional measures may be imposed on third parties to some extent.

1.11 Can a party be liable for infringement of a process patent by importing the product when the process is carried on outside the jurisdiction?

Yes, the infringement of a patent in Mexico includes the commercialisation and importation of a product derived from a patented process, even if it is carried on outside Mexico.

1.12 Does the scope of protection of a patent claim extend to non-literal equivalents?

It has been interpreted that only literal infringement is recognised under the current IP law. Infringement under the doctrine of equivalence is not expressly provided in the law; a broader interpretation of the Patent law to explore the doctrine of equivalents has not been tested before the Mexican Courts.

1.13 Can a defence of patent invalidity be raised, and if so, how? Are there restrictions on such a defence e.g. where there is a pending opposition?

According to the IP law, a defendant can file an invalidity action against a patent as a counterclaim within the same statutory term to file the response to the infringement action. An independent invalidity action can be filed, but if it is not filed along with the brief of response, it may be decided separately from the infringement.

1.14 Other than lack of novelty and inventive step, what are the grounds for invalidity of a patent?

According to the IP law, patents are valid unless proven otherwise. Thus, the IP law establishes several grounds upon which a patent can be invalidated:

- (1) When it was granted in contravention of the provisions on requirements and conditions for the grant of patents or registrations of utility models and industrial designs. Said requirements and conditions for the grant of patents and registrations are those established in articles 16, 19, 27, 31 and 47 of the IP law (novelty, obviousness and utility).
- (2) When it was granted in contravention of the provisions of the law in force at the time when the patent or registration was granted. The nullity action based on this section may not be based on a challenge of the legal representation of the applicant when prosecuting and obtaining a patent or a registration.
- (3) When the application is abandoned during its prosecution.
- (4) When granted by error or serious oversight, or when it is granted to someone not entitled to obtain it. The nullity action mentioned under (1) and (2) may be filed at any time; the actions under (3) and (4) must be filed within five years, counted from the date on which the publication of the patent or registration in the Official Gazette becomes effective.

1.15 Are infringement proceedings stayed pending resolution of validity in another court or the Patent Office?

Under certain applicable procedural rules, yes; however, the general rule is to decide upon linked cases' invalidity and infringement simultaneously.

1.16 What other grounds of defence can be raised in addition to non-infringement or invalidity?

The basis of this defence is that the proper interpretation of the patent claim does not catch the alleged infringing product or process.

Challenging the validity of patents

Under the IP law, patents are valid until the contrary is proven.

One of the most common defences in patent litigation in Mexico is to attack the validity of the allegedly infringed patent. As the patent exists, an administrative resolution is required to declare its annulment. This defence must be alleged when replying to the plaintiff's claim, by means of a counterclaim. The IMPI will give notification of the counterclaim to the party who filed the original complaint. Both the infringement claim and the counterclaim should be resolved simultaneously to preclude the possibility of contradictory outcomes. The grounds for invalidating a patent are mentioned in question 1.12.

Fair or experimental use

This refers to the non-profit use of the patented invention.

Roche Bolar Exception

In the case of medicines, a party shall be entitled to apply for the registration of a product relating to a substance or active ingredient covered by a patent pertaining to someone else, if the application is filed within three years before the corresponding patent expires. This provision, supported by the “Roche Bolar Exception”, would allow the applicant to start performing tests and experiments, in order to be ready to enter the market as soon as the patent has expired.

1.17 Are (i) preliminary, and (ii) final injunctions available, and if so, on what basis in each case? Is there a requirement for a bond?

The Mexican Patent and Trademark Law provides so-called provisional injunctions whereby the IMPI can take certain important measures against infringers. The requirement for the injunctions are:

1. Proof of a valid right.
2. Presumption of the violation of the patent.
3. Postage of a bond to guarantee damages.

If the plaintiff chooses to ask the IMPI for a provisional injunction, a bond will be fixed to warrant possible damages to the defendant. This injunction is to be petitioned in writing, and within a term of 20 days from its execution, the plaintiff is required to file a formal written claim infringement. Failure to do so will cause the plaintiff to lose the bond in favour of the defendant. This party has the right to place a counter bond to have the effects of the provisional injunction stopped. The defendant has the right to allege whatever he may deem pertinent with respect to the provisional injunctions within a term of 10 days from the day of the execution.

1.18 On what basis are damages or an account of profits assessed?

The IP law contemplates a claim for damages and lost profits in a civil law action. Damages and lost profits start accruing from the date on which the existence of an infringement can be proven. Even though claims for damages involve a lengthy proceeding in addition to the administrative infringement action, the wording of Mexican laws intends to provide fair compensation to the affected party.

The IP law establishes that the award to the plaintiff in infringement cases cannot be less than 40% of the sale price to the public of each infringing product or service. However, to be allowed to claim damages, the affected title holder must have a final decision declaring the violation of the IP right.

1.19 What other form of relief can be obtained for patent infringement? Would the tribunal consider granting cross-border relief?

Orders to stop the infringement activity, fines, and closure of the facilities where the infringement activities take place constitute other forms of relief. Costs and attorneys’ fees can be recovered in a civil claim for damages and lost profits. This takes place after the IMPI has declared the administrative infringement. The Civil Courts follow a specific scheme for reasonable attorneys’ fees, regardless of whether this table reflects the actual fees charged.

Criminal sanctions in the event of recidivism are also contemplated in the IP law.

1.20 How common is settlement of infringement proceedings prior to trial?

It is very unusual to settle cases before the decision is reached, because there are very few incentives for both parties to settle; this is because contingency derived from the infringement proceedings requires a final decision and this would be a long period of time; therefore, neither plaintiff nor defendant would face the corresponding recovery/contingency of damages as an actual or imminent situation.

1.21 After what period is a claim for patent infringement time-barred?

The IMPI’s current criterion is that the time limit for seeking a remedy is during the life term of the patent. Once the patent has expired, an action may not be brought for events that took place before the end of the life term. A defence of laches has not been tested before the Courts; therefore, legally speaking, a specific time limit exists in the IP law to bring an infringement action during the life term of the patent.

However, there is a two-year limitation period to pursue a civil action for damages; therefore, this statutory term to claim damages should be taken into consideration when looking at the timing to file infringing actions.

1.22 Is there a right of appeal from a first instance judgment, and if so, is it a right to contest all aspects of the judgment?

Appeals against the IMPI can be brought either before the specialised IP Division of the Federal Administrative Court, or before the IMPI itself through a review recourse. Decisions by either Court can be appealed in a final stage before Federal Circuit Courts.

1.23 What are the typical costs of proceedings to first instance judgment on (i) infringement, and (ii) validity? How much of such costs are recoverable from the losing party?

Government fees are minimal in the administration of patent infringements, and there are no government costs in the subsequent appeal stages.

Costs and attorneys’ fees may be recovered in a civil claim for damages and lost profits.

1.24 For jurisdictions within the European Union: What steps are being taken in your jurisdiction towards ratifying the Agreement on a Unified Patent Court, implementing the Unitary Patent Regulation (EU Regulation No. 1257/2012) and preparing for the unitary patent package? For jurisdictions outside of the European Union: Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your jurisdiction?

Needless to say that Mexico is not part of the European Union, but as clarification, there is no binding mandatory provision in the Mexican legal system that would oblige the IMPI and the Mexican Courts to recognise foreign judgments related to patents; this applies for infringement and validity rulings abroad.

However, those decisions in jurisdictions abroad would be evaluated and can be persuasive as documentary evidence.

In some cases, if the factual patterns and evidence are very similar to the case under review in Mexico, the case ruled in another jurisdiction may have relevant weight when the case is decided in Mexico.

2 Patent Amendment

2.1 Can a patent be amended *ex parte* after grant, and if so, how?

According to article 61 of the Industrial Property Law, the text or drawings of a granted patent may only be amended by the patent owner in the following circumstances:

- I. to correct any obvious or form errors; and
- II. to limit the scope of the claims.

The authorised changes shall be published in the Official Gazette.

An amendment after allowance is requested in writing to the Mexican Patent Office, briefly explaining the reasons underlying the errors that are being corrected or the limitations being introduced to the claims.

2.2 Can a patent be amended in *inter partes* revocation/invalidity proceedings?

In an invalidity action requested by a third party, which may result in a partial nullity of the patent limiting the scope of the patent, a voluntary amendment would be allowed in an *inter partes* proceeding if both parties agree and if the general rules of the civil law are followed.

2.3 Are there any constraints upon the amendments that may be made?

The amendments are restricted to correct any obvious or formal errors, and to limit the scope of the claims.

3 Licensing

3.1 Are there any laws which limit the terms upon which parties may agree a patent licence?

Pursuant to article 63 of the Mexican Industrial Property Law, it is possible to record a licence either onto a granted patent or in a pending application, so that the same may be opposed against third parties.

The limitation to the terms upon which parties may agree a patent licence are found in article 66, which establishes that the term of the licence may not exceed the natural term of the patent itself and may not be recorded when a patent has already elapsed.

Article 67 establishes the chance for the owner to grant further licences unless expressly agreed to the contrary.

It is important to mention that the law indicates that the licensee may exert defensive rights over the patent, unless specifically accorded, while working by licensee inures for the benefit of the licensor.

Finally, in regard to the cancellation of the licence recordal, the Mexican Industrial Property Law establishes that the cancellation occurs when:

- 1) the same should be requested by both the licensee and the licensor jointly;
- 2) the patent lapses or is declared null; or
- 3) by a Court order.

3.2 Can a patent be the subject of a compulsory licence, and if so, how are the terms settled and how common is this type of licence?

The following provisions of the Mexican Law of Industrial Property are relevant with regard to compulsory licences. Article 70 of the Mexican Law of Industrial Property states that after three years starting from the date of grant of the patent, or four years from the filing date, whichever is later, anyone may request from the IMPI the grant of a compulsory licence when it has not been used, except if it duly justifies an exit.

The same article also establishes that there will be no grant of a compulsory licence when the holder of the patent or a licensee has been carrying the importation of the patented product or the product obtained by the patented process. Further, article 69 states that the working of a patent by a licensee will be deemed to be worked by its holder, provided that the licence was recorded with the IMPI. Article 71 states that the party applying for a compulsory licence shall have the technical and economical capacity to efficiently work the patented invention.

On the other hand, Article 72 establishes that before the grant of the first compulsory licence, the IMPI will provide the patentee with the opportunity to begin working the patent within a term of one year from the date of personal notification given to him. Following a hearing with the parties, the IMPI will decide on the grant of a compulsory licence, and if the IMPI decides to grant it, it will set forth its duration, conditions, field of application and amount of royalties that correspond to the holder of the patent.

We are not aware that any compulsory licence has been granted in recent years. In any event, the royalties are established by the IMPI after a hearing with the parties, and they should be fair and reasonable.

4 Patent Term Extension

4.1 Can the term of a patent be extended, and if so, (i) on what grounds, and (ii) for how long?

The Mexican Regulations do not establish the possibility of patent life term extensions. However, it is important to mention that there are obligations derived from international treaties such as NAFTA, which establishes the possibility of patent life term extensions when the Health Authority delays the process to obtain a marketing authorisation for a patented product.

Please note that no one has tried to obtain a patent life term extension through the application of this possibility regulated by international treaties.

Therefore, in the eventual case that a person would try this kind of action derived from the delay by the Health Authority in the process to obtain a marketing authorisation for a patented product, we consider that it is necessary to argue the direct application of the international treaties as a supreme law which will in fact rule over domestic law.

Notwithstanding that, the IMPI does not allow an extension on patent terms, as said term extensions are not provided in the Patent law *per se*; please be advised that our law firm has achieved corrections

gaining more time in the expiration date of patents through legal proceedings only for **pipeline patents**, granted in accordance with Transitory Article 12 of the Mexican Law for the Promotion and Protection of Industrial Property Law, enacted back in June 1991.

Mexico signed already as in the process to implement the Transpacific Partnership (TPP), a free trade agreement with 11 countries, wherein the IP Chapter; there is the proposal to include restoration terms for patents derived from delay in the patent prosecution of the approval process.

5 Patent Prosecution and Opposition

5.1 Are all types of subject matter patentable, and if not, what types are excluded?

The following subject matter is not patentable in Mexico:

- I. essentially biological processes for obtaining, reproducing and propagating plants and animals;
- II. biological and genetic material as found in nature;
- III. animal breeds;
- IV. the human body and the living matter constituting it; and
- V. plant varieties.

On the other hand, the following subject matter is not considered as invention in Mexico:

- I. theoretical or scientific principles;
- II. discoveries that consist of making known or revealing something that already existed in nature, even though it was previously unknown to man;
- III. diagrams, plans, rules and methods for carrying out mental processes, playing games or doing business, and mathematical methods;
- IV. computer programs;
- V. methods of presenting information;
- VI. aesthetic creations and artistic or literary works;
- VII. methods of surgical, therapeutic or diagnostic treatment applicable to the human body and to animals; and
- VIII. juxtaposition of known inventions or mixtures of known products, or alteration of the use, form, dimensions or materials thereof, except where in reality they are so combined or merged that they cannot function separately, or where their particular qualities or functions have been so modified as to produce an industrial result or use not obvious to a person skilled in the art.

5.2 Is there a duty to the Patent Office to disclose prejudicial prior disclosures or documents? If so, what are the consequences of failure to comply with the duty?

There is no duty for the IMPI to disclose prejudicial prior documents.

5.3 May the grant of a patent by the Patent Office be opposed by a third party, and if so, when can this be done?

In a period of six months after the publication of the patent application, information related to patentability of an invention can be filed before the IMPI by a third party. If filed, the information may be considered at the Examiner's discretion and it will not suspend the application process. The person filing the information

will not be considered a party and will not have access to the patent file or immediate legal standing to challenge a granted patent.

After a patent is granted, anyone can inform the IMPI of causes of invalidity. The authority may consider such information discretionally to initiate an *ex officio* cancellation proceeding.

5.4 Is there a right of appeal from a decision of the Patent Office, and if so, to whom?

Appeals against decisions of the IMPI can be brought either before a specialised IP Division of the Federal Court for Tax and Administrative Affairs, or before Federal District Judges. Decisions by either Court can be appealed in a final stage before Federal Circuit Courts.

5.5 How are disputes over entitlement to priority and ownership of the invention resolved?

Disputes over entitlement to priority and ownership of the invention are resolved by the IMPI. A final decision issued by the IMPI may be appealed (see question 5.4).

5.6 Is there a "grace period" in your jurisdiction, and if so, how long is it?

The Mexican Law of Industrial Property contemplates a one-year grace period, as follows:

"Article 18. The disclosure of an invention shall not prevent it from continuing to be considered new where, within the 12 months prior to the filing date of the patent application or, where applicable, the recognised priority date, the inventor or his assignee has made the invention known by any means of communication, by putting it into practice or by displaying it at a national or international exhibition. When the corresponding application is filed, the evidentiary documents shall be included in the manner laid down in the Regulations under this Law.

The publication of an invention contained in a patent application or in a patent granted by a foreign office shall not be regarded as corresponding to any of the situations referred to in this article."

In order to benefit from the grace period, it is required to file a declaration stating the date, place and means of disclosure, together with the Mexican patent application.

5.7 What is the term of a patent?

The term of a patent is 20 years from the filing date. No extensions of term are available in Mexico.

6 Border Control Measures

6.1 Is there any mechanism for seizing or preventing the importation of infringing products, and if so, how quickly are such measures resolved?

The Mexican Industrial Property Law establishes that there are available injunctions for infringement of patent rights on a provisional and permanent basis in Mexico. The Customs Law in its articles 148 and 149 establishes the rules for implementing the same with the Mexican Customs.

Generally speaking, in order to grant a preliminary injunction, it is necessary to comply with certain requisites, such as that the holder of the Industrial Property right has applied to the products, packaging or wrapping of the products protected by the patent, the marking indications, or, by some other means, has made it public knowledge that there is a protected Industrial Property right.

Other pertinent requisites can be found in article 199*bis* 1, which requires that the requesting party also complies with the following:

- I. Prove that they hold a patent right and any of the following in addition:
 - a) The existence of an infringement to his right.
 - b) That the infringement to his right will be imminent.
 - c) The existence of the likelihood of irreparable damages suffered.
 - d) The existence of justified fear that the evidence will be destroyed, concealed or altered.
- II. Grant sufficient bond in order to warrant the damages which would be caused to the person against whom the measures are demanded.
- III. Provide the IMPI with the information necessary for the identification of the goods or establishments in which or where the infringement to Industrial Property rights is occurring.

In regard to the scope of the injunctions, the IMPI may order the alleged infringer or third parties to suspend or discontinue the acts constituting a violation of the provisions of Law and the seizure of goods such as:

1. Objects manufactured or used illegally.
2. Objects, wrappers, containers, packaging, paperwork, advertising material and similar articles that infringe any Industrial Property right protected by the Industrial Property Law.
3. Signs, labels, tags, paperwork and similar articles that infringe any of the rights protected by the Industrial Property Law.
4. Implements or instruments intended or used for the manufacture, preparation or production of any alleged to infringe relevant Industrial Property rights. It is important to mention that the alleged infringer is entitled to file a counter bond to obtain the lifting of the preliminary injunctions.

In regard to the time frame, once the legal requisites are fulfilled, normally preliminary injunctions are adopted and put into practice in a rather quick fashion that may range from two to seven days, depending on the need to implement the same, i.e. seizures at Customs, due to the nature of the importation process and the need for a rather quick implementation, may take 48 hours.

Permanent injunctions are declared once the administrative infringement proceeding is finally decided.

7 Antitrust Law and Inequitable Conduct

7.1 Can antitrust law be deployed to prevent relief for patent infringement being granted?

There is no precedent in Mexico of antitrust, unfair competition or business-related tort actions brought against patentees for the use of a patent. Courts generally consider that the use of a state-given right cannot constitute a violation in these areas.

7.2 What limitations are put on patent licensing due to antitrust law?

An action could theoretically be brought for activities falling outside the scope of a patent, such as non-competition agreements for products that are not covered by the claims, product-tying within that scope, or unfair competition activities such as advertising that a product is better than an alternative for the sole reason of it having a patent. Actions could also be brought before the Antitrust Commission for other forms of abuse of patent rights, such as clearly unfounded attempts to enforce a patent.

8 Current Developments

8.1 What have been the significant developments in relation to patents in the last year?

- **The Mexican Supreme Court ruled on the required legal standing to question marketing authorisations in violation of patents and health law Regulations.**

The Supreme Court addressed many legal issues relevant for the decision; however, to be concise, we will refer to only some of them, as follows:

- i) although it was not the main issue which was subject to analysis, the Supreme Court states that a patent holder has a subjective right that is transformed in proper legal standing to questioning any proceeding that may violate its exclusive rights; and
- ii) in the absence of a subjective right such as a patent, based on the human right conferred in the Mexican Constitution to a healthcare or a pharmaceutical company having a valid marketing authorisation for an innovative medicine, these companies have the proper legal standing to question and request the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) the issuance of an approval for a bioequivalent product only if it fully complies with all the applicable law and regulations, otherwise the healthcare right provided in the Mexican Constitution would be jeopardised.

However, this Supreme Court precedent did not order COFEPRIS to cancel the generic approval, and also established that COFEPRIS was not bound to call the innovator to the generic approval proceeding. This is a valuable and positive case law which confirms that patent holders have the legal standing to question marketing authorisations that may violate the exclusive rights, but it is also based on the human right to health which is recognised in the Mexican Constitution and which recognises a pharmaceutical company as part of the health system, in order to prevent health risks. It is also entitled to question and request COFEPRIS to observe all the applicable rules and regulations for the approval of a medicine.

- **The Novartis Case in Mexico.**

The Circuit Court ruled on behalf of Novartis considering that Novartis had the proper legal standing to request COFEPRIS to observe the patent listed in the Linkage Gazette, and requested the observance of the Linkage Regulation. In addition, the Circuit Court agreed with the allegation that article 167*bis* of the Linkage Regulation is unconstitutional, as it does not provide the right of the titleholder of the patent to be heard during the approval process.

This is the first case in Mexico which decides unconstitutionality against a provision of the Linkage Regulation and on behalf of the patent holder.

As the decision of interest is a final declaration of unconstitutionality of a provision that was applied in prejudice of Novartis, legally speaking, COFEPRIS cannot apply again and, in the same manner, this provision against Novartis even in different cases. This would mean that derived from this decision, as from now, Novartis is entitled to request participation in “any” approval proceedings by third parties based on article 167*bis* of the Health Regulation that was declared unconstitutional on behalf of Novartis.

8.2 Are there any significant developments expected in the next year?

- Proposal of the Mexican Patent law to broaden the scope of compulsory licences.
- The Mexican Congress is already discussing the eventual ratification and therefore the implementation of the TPP to our domestic law relevant issues regarding patent terms, patent issues, linkage and patent data protection.

8.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

- Patent prosecution highways are becoming more usual.
- Importers of medicines have abused the experimental and Roche Bolar Exceptions; the Courts or the corresponding administrative authorities should now establish its limits.
- Enforcement of the Linkage Regulation on formulations and usage of patents is a “hot topic”.
- IP and human rights constitute a day-to-day argument before the Mexican Courts.
- Challenging patents based on patentability requirements rather than the traditional formal arguments is more common.
- Precedents on the interpretation of the Roche Bolar Exception and legal standards to challenge a patent are expected in the coming months.

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Alejandro Luna holds litigation specialisation degrees from the Universidad Panamericana, and a Master's degree in Intellectual Property Law at the Franklin Pierce Law Centre in Concorde, New Hampshire, U.S.A.

He has proactively participated in cases against the unconstitutionality and inefficiency of certain amendments to the Federal Law of Administrative Proceedings in Mexico, which have precipitated challenges to the resolutions by the Mexican Institute of Industrial Property.

Mr. Luna is also the 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 the jurisdiction for litigation to Civil Courts in infringement cases, and to Administrative Courts for cases related to the annulment of trademark registrations or patents.

Mr. Luna is the author of several articles on patents, litigation and regulatory issues that have been published both in Mexico and abroad. Mr. Luna is a distinguished member of several associations and is currently the Vice-President of the Mexican Association for the Protection of Industrial Property. He was named as one of the World's Leading Patent Law Practitioners in its 2007 Guide. Currently, Mr. Luna is a Partner in charge of the Appeals Department and Co-chair of the Life Sciences group at OLIVARES, and he is a part-time Professor at the National University (UNAM).

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Sergio L. Olivares, Jr. joined OLIVARES in 1987, becoming a Partner in 1994 and Chairman of the Management Committee in 2009. He leads the firm with strength and a commitment to transparency, client satisfaction, and personal service.

Mr. Olivares' work at OLIVARES is extensive, and he has vast experience in the prosecution and litigation of intellectual property rights, particularly trademarks, copyrights, patents and unfair competition. He has specialised his practice in all types of intellectual property law, but works closely with the Patent group. Mr. Olivares is highly recommended by leading industry titles and rankings as a leader in IP. He has been influential in ensuring that the firm remains highly innovative as we have added new practice areas and industry groups that offer more complex types of work such as regulatory advice and administrative litigation, in addition to the establishment of the Life Science and IT industry groups.

After his graduate work, Mr. Olivares trained with two prominent IP law firms in New York City, Morgan & Finnegan and Kenyon & Kenyon, before joining OLIVARES. This deep understanding of US intellectual property law allows him to offer clients clear comparative analyses of the US and Mexican legal systems and explain complex matters in a way that suits our international clients' needs.

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- Franklin Pierce Law Center – Intellectual Property, 1993.
- Universidad Intercontinental – *Juris Doctor*, 1991.



OLIVARES began in 1969 as an intellectual property boutique. Today, the IP Practice serves many different industries, receives numerous awards for excellence in legal service, and leads the charge in protecting clients' valuable IP assets. Whether navigating complex pharmaceutical patent regulations, developing trademark protection strategies, or litigating copyright disputes, OLIVARES gets results.

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