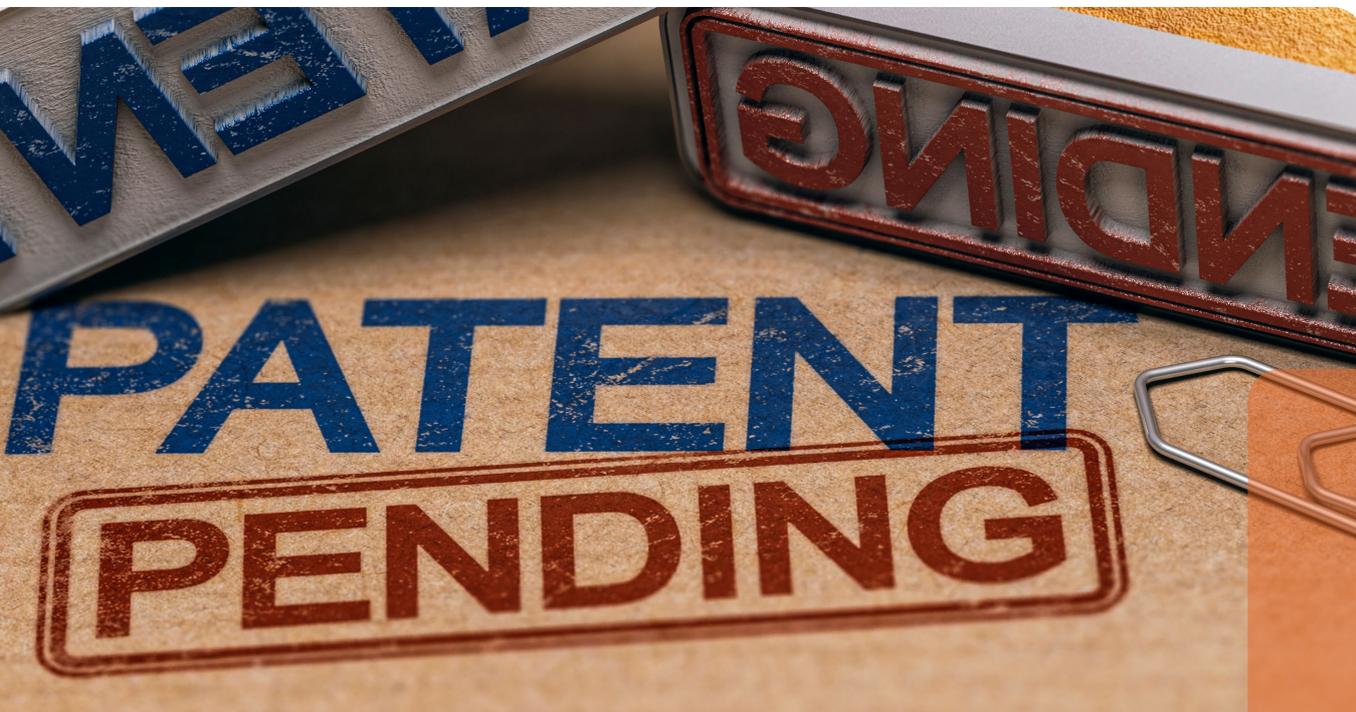


**International
Comparative
Legal Guides**



Patents

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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?

As of November 5, 2020, the Industrial Property Protection Law (IPPL) provides the possibility of enforcing patent rights either through an administrative infringement action before the Mexican Patent Office (IMPI) or a civil claim before the Civil Courts.

The traditional venue to enforce a patent is through administrative proceedings (infringement action) before the IMPI, which is not a Court of Law, but a federal administrative entity. The decisions of this agency on patent infringement cases can be appealed by any one of the intervening parties with a specialised IP Court. The decision issued by a specialised IP Court can be appealed before the Federal Circuit Courts in Mexico City; however, the case is turned randomly by a computer system. By territorial jurisdiction, IP matters are mainly decided in Mexico City.

In the administrative venue, it is possible to request the IMPI to quantify the damages caused by the infringer through a special incidental proceeding once the infringement is declared and before the appeals with the specialised IP Court and the Federal Circuit Courts are solved. Once the damages have been quantified by the IMPI, it is necessary to request a Civil Court to execute the Mexican Trademark Office (MTO)'s resolution.

The civil venue allows the patentee to file a claim for damages directly with a Civil Court without the requirement of having a declaration of infringement issued by the IMPI. This means that it is no longer required to have a decision from the IMPI before submitting any civil action against an infringer for the payment of damages. The Civil Courts are now empowered to solve disputes in accordance with the IPPL, which means that the Civil Court will decide on the infringement and the awarding of damages at once.

The downside of the civil venue is that the Civil Courts are not empowered to solve invalidity actions against IP rights. Therefore, if an invalidity action is filed with the IMPI against the patent, the civil procedure will be suspended until the invalidity action is solved beyond the shadow of any appeal.

The filing of an infringement action before the IMPI or a Civil Court provides the defendant with legal standing to file an

invalidity action against the patent being enforced. Therefore, the claimant may be influenced to choose the administrative venue to prevent the infringement action from being suspended.

1.2 Can the parties be required to undertake mediation before commencing court proceedings? Is mediation or arbitration a commonly used alternative to court proceedings?

The parties are not required to undertake mediation before an infringement action; however, conciliation may be requested by any party of an existing litigation with the IMPI and, if the counterparty accepts, two conciliation meetings will be held, in which the IMPI will try to “conciliate” the parties’ positions, without expressing any possible decision about the merits of the case, to reach a settlement.

If the parties reach a settlement, it needs to be formalised by the IMPI, and in such case, the settlement agreement will be enforceable. Conciliation proceedings will not suspend the litigation, which will continue normally.

This option has been poorly explored by patent infringement parties; however, we consider that it is a reasonable option that could benefit both parties and save time and costs.

After a claim is filed in the civil venue, the Court will order a conciliation hearing where the parties may or may not reach a settlement. If the parties do not reach a settlement, the Court will continue with the prosecution of the claim.

1.3 Who is permitted to represent parties to a patent dispute in court?

At the first stage before the IMPI, there is no legal requirement to represent individuals or companies in patent disputes, other than the formalities of the corresponding Power of Attorney, but there is no registration at the Bar or certifications required to represent a party in patent litigation at the first stage of the administrative proceedings before the IMPI, namely: infringement; and invalidity actions.

However, at the further two appeal stages – the nullity trial before the Federal Court for Administrative Affairs (FCAA), and the Amparo suit before the Circuit Courts – the lawyers representing the parties are required to be attorneys-at-law, qualified at a federally licensed law school.

In the civil venue, it is required for the lawyers representing the parties to be attorneys-at-law, qualified at a federally licensed law school.

1.4 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?

In the administrative venue, there is a requirement to pay Government fees to commence a proceeding (patent infringement or invalidity) before the IMPI. The Government fees usually amount to approximately US\$73. The proceeding before the IMPI usually lasts two years. This is the first stage; at least two additional stages are applicable.

In the civil venue, Government fees are not required to be paid.

1.5 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 necessary for the verification of facts that may constitute a violation of one or more of the rights protected by the IPPL or the administrative declaration procedures.

When the owner concerned or the alleged infringer has submitted sufficient evidence to reasonably support its claims and has specified evidence relevant to the substantiation of its claims that are under the control of the opposing party, the IMPI may order the submission of such evidence during the proceedings and, where applicable, this authority should ensure the confidentiality of this information.

The Civil Courts are also empowered to order the submission of any evidence that may be essential to solve the controversy and are compelled to keep its confidentiality, if necessary.

1.6 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 or the Civil Court.

The applicable regulations do not facilitate a pre-trial stage; therefore, there is no evidence produced in such stage, but its preparation may be necessary.

1.7 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 and follow the 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 no, parties cannot change their pleaded arguments, unless there are supervening or unknown facts.

1.8 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, there can be two further stages of appeals before the Courts, lasting no less than three further years.

1.9 Is there any alternative shorter, flexible or streamlined procedure available? If so, what are the criteria for eligibility and what is the impact on procedure and overall timing to trial?

The Conciliation proceeding before the IMPI or the Civil Courts is a shorter and more streamlined procedure in resolving the controversy.

The civil action is a shorter alternative in comparison to the administrative procedure; however, it can be hampered if an invalidity action is filed as a counterclaim.

1.10 Are judgments made available to the public? If not as a matter of course, can third parties request copies of the judgment?

The IMPI does not make the judgments of patent infringement trials or any proceeding available to the public until they are final and beyond the shadow of appeal, and some information regarding the decision remains confidential, especially if the parties request this. The IMPI only publishes the conclusion of the judgment (depending on whether an infringement or invalidation was declared) in the IP Gazette, and not the reasoning of the judgment.

The Civil Courts publish versions of their judgments, but delete confidential information, such as the name of the parties.

1.11 Are courts obliged to follow precedents from previous similar cases as a matter of binding or persuasive authority? Are decisions of any other jurisdictions of persuasive authority?

Only jurisprudence is mandatory for the Courts. In fact, as the IMPI is an administrative authority, it is not part of the judiciary, thus they are not bound to follow jurisprudence. Briefly speaking, jurisprudence is construed by five rulings issued unanimously by the same Court or by the Supreme Court *en banc*, but this jurisprudence is mandatory for lower Courts from the judiciary. The IMPI has stated that as it is an administrative authority, jurisprudence and judicial precedents are not compulsory for the lower courts when deciding the administrative proceedings, and are only persuasive. Legally speaking, the IMPI is right; however, as the lower courts are acting as Judges when deciding contentious cases, ethically and as a matter of principle, they should observe binding jurisprudence, as the higher appeal Courts will do so; otherwise, they would only be delaying the application of the binding jurisprudence.

On the other hand, Civil Courts are bound to follow legal precedents. This will be an important issue in future civil actions, as mentioned in question 1.1 above.

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

The IMPI is considered the only first-instance specialised authority that can solve patent enforcement proceedings in the first instance. As of November 5, 2020, the IPPL allows Civil Judges, either federal or local, to decide on damages without exhausting the patent infringement proceeding, which forces them indirectly to rule on the infringement; these Judges are not specialised in IP Law.

In January 2009, a specialised IP Division at the Federal Administrative Courts began operating. This Division has jurisdiction to review all cases resolved by the IMPI and based

on the IP Law, 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 will have no technical background.

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

These two last authorities will not review the decision of the Civil Courts. In those cases, the Superior Civil Tribunal and finally the Federal Civil Circuit Courts will decide on the appeals filed, with neither of them having IP-specific technical backgrounds.

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

- (1) Any patentee or licensee (unless expressly forbidden from doing so) has the right to prosecute a suit against a third party infringing their rights. A distributor may not bring a suit for infringement.
- (2) An accused infringer may counterclaim patent invalidity under formal or technical considerations, upon receiving the infringement suit before the IMPI or Civil Courts, but it is not possible to request an additional judicial ruling or declaration.
- (3) 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.
- (4) Amendments to the patent law allow anyone to request the IMPI to officially initiate the cancellation proceedings against patents.
- (5) Simple legal standing, namely the mere business or commercial activity to challenge the validity of a patent, is tested before the Courts. Recently, in some pharmaceutical cases, if the validity of a patent is not challenged as a response to an infringement action, the Federal Courts determined that it is necessary to demonstrate a direct affectation to prove legal standing.

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

In Mexico, non-infringement declarations are not available.

1.15 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, inducement to infringe or any other indirect type of infringement. There is some room, however, 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 injunctions may be imposed on third parties to some extent.

1.16 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.

1.17 Does the scope of protection of a patent claim extend to non-literal equivalents (a) in the context of challenges to validity, and (b) in relation to infringement?

For many years, it has been interpreted that only literal infringement is recognised under the current IP Law. Infringement under the doctrine of equivalents is not expressly provided in the law; a broader interpretation of the patent law to explore the doctrine of equivalents is required.

Nevertheless, recently a Circuit Court in Mexico ruled on behalf of a pharmaceutical company, considering the peripheral interpretation method as a precedent, but this is not mandatory.

The Circuit Court considered that, according to the Mexican rules and regulations, the intention of the legislator to grant the claim a fundamental role in the definition of the subject matter of the patent is very clear, since this rule allows the State to protect the industrial property to a greater extent and to prevent actions affecting such exclusivity or that constitute unfair competition and, if applicable, eradicate this practice by means of the imposition of the corresponding sanctions.

Therefore, the level of a possible infringing action shall be decreed based on the identification with the scope of protection of the claims that shall determine the existence of an eventual infringement due to identity or equivalence.

Although this ruling does not exactly implement the U.S. doctrine of equivalence, this is a positive start. Concerning challenges to validity, there is no precedent that establishes that the scope of protection of a patent is extended to non-literal equivalents. Further, the law does not expressly recognise equivalents. However, from a broad interpretation of the patent law, it might be possible to raise an argument in favour of the applicability of the doctrine of equivalents in regard to invalidity actions.

1.18 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? Are the issues of validity and infringement heard in the same proceedings or are they bifurcated?

Although the issues of infringement and validity are prosecuted in different filings with the IMPI, they are decided at the same time, especially if the invalidity action is filed as a counterclaim; specifically, if filed at the same time as the response to the infringement action. This administrative venue will continue.

The Civil Court allows patent owners to claim damages directly without waiting for an administrative decision. In this venue, in case an invalidity action is filed, the IMPI will be the only one entitled to rule over it and the civil case will be stayed until a decision is reached.

1.19 Is it a defence to infringement by equivalence that the equivalent would have lacked novelty or inventive step over the prior art at the priority date of the patent (the "Formstein defence")?

As explained in question 1.17, the doctrine of equivalence is still developing in Mexico. The law does not expressly provide a

defence to infringement by equivalence. However, the interpretation of the law provisions concerning patentability conditions and patentable subject matter, enable the application of the “*Formstein* defence”.

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

The IP Law, which was in force until November 5, 2020, provides 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.
- (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 actions mentioned under (1) and (2) may be filed at any time; the actions under (3) and (4) must be filed within five years and counted from the date on which the publication of the patent or registration in the Gazette becomes effective.

These causes of invalidation can be enforced against patents granted before November 5, 2020.

Now, in accordance with the IPPL, in force as of November 5, 2020, a patent can be only declared invalid:

- (1) when the subject matter is not considered an invention, or in case of non-patentable subject matter, lack of novelty, inventive step or industrial applicability;
- (2) due to lack of disclosure;
- (3) due to lack of support;
- (4) in case of divisional applications, when granted against new rules for them;
- (5) when broadening the scope of protection originally allowed during a correction proceeding;
- (6) due to mistakes recognising priority rights that otherwise could result in a lack of novelty or inventive step;
- (7) in double patenting cases; and
- (8) when granted to a person that was not entitled to apply for it.

None of these actions have statutes of limitations.

The first set of invalidity actions mentioned above will be applied only for patents granted before November 5, 2020. Any patent granted after that date may only be challenged using the second set of invalidity actions.

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

The general rule is to decide linked cases’ invalidity and infringement simultaneously in the administrative venue. As to the new civil venue, please see question 1.1 above.

1.22 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. The IP Law does not contemplate affirmative defences such as laches.

1.23 (a) Are preliminary injunctions available on (i) an *ex parte* basis, or (ii) an *inter partes* basis? In each case, what is the basis on which they are granted and is there a requirement for a bond? Is it possible to file protective letters with the court to protect against *ex parte* injunctions? (b) Are final injunctions available? (c) Is a public interest defence available to prevent the grant of injunctions where the infringed patent is for a life-saving drug or medical device?

Preliminary injunctions can be requested with the IMPI before the filing of the infringement action or at any time during prosecution. The proceeding is *in audiita altera pars* with no formal hearing as it is followed up in writing.

For the implementation of the preliminary injunctions, the IMPI will analyse the appearance of a *prima facie* case and the non-violation of public order provisions. The IMPI will also take into consideration the seriousness of the infringement and the nature of the preliminary injunction. For such analysis, the party moving forward with the injunction must:

- Prove that they own an exclusive right, and:
 - the potential existence of an infringement to such right;
 - that violation of such right is imminent;
 - the possibility of the right being irreparably damaged; or
 - a well-founded fear that the evidence may be destroyed or hidden.
- Post a bond to warrant the possible damages to the defendant. The amount of the bond will be fixed by the IMPI considering the evidence filed by the plaintiff, and the IMPI may request the plaintiff to extend the bond after the implementation of the injunctions.
- Provide the necessary information to identify the establishment goods subject to the injunction.

Preliminary injunctions are available on an *ex parte* basis. However, after the defendant is served with the injunctions, the alleged infringer is entitled to the lifting of preliminary injunctions by placing a counterbond, in which case the MTO will analyse if the damages that the alleged infringer may suffer with the implementation of the injunctions are greater than the damages that the plaintiff may suffer. 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.

Once the case is resolved by the IMPI and infringement is found, definitive injunctions are imposed on the infringer. It is possible to file a constitutional trial (*Amparo*) before the Federal District Courts to try to stop the imposition of preliminary injunctions. However, the admissibility and likelihood of success of such an action has to be assessed on a case-by-case basis.

There is no specific remedy to prevent an injunction in the case of life-saving drugs or medical devices; however, compulsory licences are available in Mexico. Please see question 3.2.

1.24 Are damages or an account of profits assessed with the issues of infringement/validity or separately? On what basis are damages or an account of profits assessed? Are punitive/flagrancy damages available?

According to the IPPL, the awarding of damages for the violation of an IP right shall not be lower than 40% of the commercial value of the infringing goods, the profits of the infringer, the lost profits of the patentee or the fee that the infringer should have paid for a licence.

The awarding of damages is assessed through a special incidental proceeding with the IMPI after the infringement is

declared. In the case of the Civil venue, the awarding of damages is assessed with the issues of the infringement.

In April 2018, the Mexican Supreme Court published a decision relating to the interpretation of the so-called 40% rule for calculating damages.

The decision expressly establishes that the validity and constitutionality of the provision establishing the 40% rule, and the rule itself, is not questioned by the Supreme Court, but the ruling establishes that the concept of damages is separate from the amount of the compensation and that the plaintiff is required to prove, on a case-by-case basis, evidence of actual harm, material and immaterial and a “*causal nexus*” between the infringing activity and the damages suffered by the IP owner.

Even though this ruling was issued during the validity of the former IP Law, we consider that it will be used by the IMPI and the Courts to analyse the quantification of damages in infringement actions filed under the IPPL.

1.25 How are orders of the court enforced (whether they be for an injunction, an award of damages or for any other relief)?

In the event of a second or subsequent offence, the fines previously imposed on the offender shall be doubled. A second or subsequent offence refers to every subsequent infringement to the same provision, after the first infringement is declared in a final resolution.

Likewise, closures may be ordered in the decision that rules on the infringement, in addition to a fine or without a fine having been imposed. There shall be grounds for permanent closure when the establishment has been temporarily closed twice within a period of two years if, during said period, the infringement is repeated regardless of whether the location thereof has changed.

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

Other forms of relief include orders to stop the infringement activity, fines and closure of the facilities where the infringement activities take place. 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.

1.27 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 which would require a long period of time. Therefore, neither plaintiff nor defendant would face the corresponding recovery/contingency of damages as an actual or imminent situation.

1.28 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.

1.29 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.

Appeals against Civil Courts can be brought with the Superior Civil Tribunal and its decisions can be appealed before the Federal Civil Circuit Courts.

1.30 What effect does an appeal have on the award of: (i) an injunction; (ii) an enquiry as to damages or an account of profits; or (iii) an order that a patent be revoked?

As a matter of principle, when filing an appeal, the plaintiff can request the Federal Court for Administrative Affairs or a District Judge to suspend the effects of the resolution issued in the first instance.

In the case of injunctions, the plaintiff is able to request the courts to order the IMPI to refrain from collecting the fine imposed as a result of the infringement, but the plaintiff will not be allowed to sell or use the infringing goods.

If an appeal is filed against a resolution awarding damages, the decision of the appeal can either revoke the awarding of damages, modify the amount of damages awarded or order the replenishment of the procedure.

If a patent is invalidated by the IMPI, the appeal with the Federal Court for Administrative Affairs can have the effect of revoking the decision issued by the IMPI and recognise the validity of the patent.

1.31 Is an appeal by way of a review or a rehearing? Can new evidence be adduced on appeal?

The two options are available; if the resolution is challenged through a Review Recourse before the IMPI itself, the Head of the Litigation Department will review that it was issued accordingly with the provisions of the law, and consider the evidence in the file only.

If the resolution is challenged through an appeal before the Federal Court for Administrative Affairs, the parties are able to submit new evidence to prove that the resolution is illegal or that certain technical aspects of the patent were not duly analysed by the IMPI.

1.32 How long does it usually take for an appeal to be heard?

The appeal process takes around one to one-and-a-half years.

1.33 How many levels of appeal are there? Is there a right to a second level of appeal? How often in practice is there a second level of appeal in patent cases?

There are three levels of appeal. A resolution can be challenged through a Review Recourse before the IMPI and this level of appeal is optional and not commonly used.

The second level of appeal – or first, depending on whether a Review Recourse was filed – is before the Federal Court for Administrative Affairs. The third level of appeal is filed with the Federal Circuit Courts.

In Mexican practice, the resolutions issued by the IMPI declaring an infringement or affecting a patent are commonly challenged up to the third level of appeal.

As for the case of civil courts, appeals can be brought with the Superior Civil Tribunal and its decisions can be appealed before the Federal Civil Circuit Courts.

1.34 What are the typical costs of proceedings to a first instance judgment on: (i) infringement; and (ii) validity? How much of such costs are recoverable from the losing party? What are the typical costs of an appeal and are they recoverable?

The Government fees for filing an invalidity or infringement amount to US\$73, approximately. We have tried in the past to recover attorney fees under the provisions of the TRIPS Agreement and NAFTA (mirror provisions in the USMCA) with disappointing outcomes. In Mexico, it is quite difficult to achieve a ruling of compensation of attorney fees, and it could entail a long litigation.

The national law specifically provides that attorney fees may not be collected for administrative litigations (such as an IP infringement action) and even if the attorney fees are awarded, they are significantly lower than the actual expenses and they must be claimed in the civil court. Therefore, there is no cost-time benefit of seeking compensation of attorney fees in Mexico.

1.35 For jurisdictions within the European Union: What is the status in your jurisdiction on ratifying the Unified Patent Court Agreement 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?

Foreign decisions are not binding to Mexican authorities; however, they are often introduced in litigation for illustrative purposes. Mexico does not have any similar mechanism to the one contained in the Unified Patent Court Agreement. The only recognition available for foreign decisions according with our civil law is in order to execute foreign decisions for purposes of obtaining payment or any other liability obligation in civil procedures; however, for the specific case of patents, this option is not available upon rule 4*Bis*, 1) and 2) of the Paris Convention.

2 Patent Amendment

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

According to the provisions of the IPPL, post-grant amendments are only allowed to correct any obvious or form errors, to delete one or more claims, or to include one or more dependent

claims within an independent claim; however, when an invalidity action has already been filed, any amendment petition will be dismissed. This was a trend in patent litigation that is now forbidden by the new law.

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

If an invalidity action is filed by a third party against a patent, it may result in a partial invalidation of the patent limiting the scope of the patent; a voluntary amendment would be allowed in an *inter partes* proceeding if both parties agree in order to settle the litigation.

It is worth mentioning that as of November 5, 2020, if an invalidity action is filed against a patent, the patentee cannot unilaterally amend the claims of the patent to avoid its invalidation; the request to amend the patent will be suspended until the invalidity action is solved beyond the shadow of an appeal.

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

The amendments under the new law are restricted to correcting any obvious or form errors, and to limiting the scope of claims as specified in question 2.1 above.

3 Licensing

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

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 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.

Patent owners may grant further licences unless expressly agreed to the contrary.

Licensees may exert defensive rights over the patent, unless specifically accorded, while working by licensee inures to the benefit of the licensor.

Finally, in regard to the cancellation of the licence recordal, the Mexican Industrial Property Law (MIPL) 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) there is 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?

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.

It is also provided 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. Furthermore, 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. The party applying for a compulsory licence shall have the technical and economical capacity to efficiently work the patented invention.

On the other hand, 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.

A compulsory licence can be also granted for emergency or national security reasons, including serious diseases declared as such by the General Health Council. The IMPI will determine that certain patents can be exploited through a compulsory licence for reasons of “public benefit”, when the lack of a licence would hinder or overvalue the production, supply or distribution of basic goods to the population. In cases of serious diseases, the General Health Council must publish a declaration of national emergency in the Official Gazette and thereafter the IMPI will issue the licence.

We consider that this type of compulsory licence is a possibility; although under the following circumstances that should be proved: hindrance; overprice; or shortage caused by the exclusivity right of the patent.

We are not aware of any compulsory licence being 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?

For applications filed in Mexico from November 5, 2020, patent owners may request from the IMPI complementary term certificates for patent applications that were granted after five years of prosecution, when the delay is imputable to the IMPI. Such petition must be filed before paying the issuance fees and the IMPI will grant one day for each two days’ delay imputable to them. Any automatic term extension provided by law taken by the applicant will be subtracted from the five-year term.

As to extensions related to delays in the granting of marketing authorisations for pharmaceutical products, the USMCA rule will not enter into force in Mexico until 2025.

In addition to the above, on October 14, 2020, the Mexican Supreme Court issued an important precedent which opens the opportunity to compensate the life term of patents due to unjustified delays during patent prosecution prior to the USMCA. However, the ruling applies and benefits the complaining party only. The decision is not binding to the IMPI, and therefore, it is expected that the IMPI will not adopt the criteria to compensate the life term of patents in similar cases without a court order. For the Mexican Courts, the precedent is not binding either, but highly persuasive. The patent was prosecuted under the rules of the former IP Law.

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:

- (1) Inventions which commercial exploitation is contrary to the public order or which exploitation should be forbidden

to protect the life or health of human beings, animals or plants, or to avoid damages to the environment, such as:

- (a) Processes for cloning human beings and its products.
 - (b) Processes for modifying the germ genetic identity of human beings and its products when they imply the possibility of developing a human being.
 - (c) Uses of human embryos for industrial or commercial purposes.
 - (d) Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.
- (2) Plant varieties and animal breeds, except for micro-organisms.
 - (3) Essentially biological processes for obtaining plants and animals and the products resulting from these processes, except for microbiological processes and their products.
 - (4) Methods of surgical, therapeutic or diagnostic treatment applicable to the human body and to animals.
 - (5) The human body and discoveries of any of its elements; however, biological material isolated from its natural environment and obtained by means of a technical process could be patentable.

On the other hand, the following subject matter is not considered an invention in Mexico (when said subject matter is claimed as such):

- (1) Discoveries, scientific theories or its principles.
- (2) Mathematical methods.
- (3) Aesthetic creations and artistic or literary works.
- (4) Diagrams, plans, rules and methods for carrying out mental processes, playing games, carrying out commercial economic activities or doing business.
- (5) Computer programs.
- (6) Methods of presenting information.
- (7) Biological and genetic material as found in nature.
- (8) Juxtaposition of known inventions or mixtures of known products, 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 to disclose prejudicial prior art or 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 two months after the publication of the patent application, information related to the 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 at its discretion 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?

This opposition is more like a third-party prior art submission. The person filing it is not considered part of the patent prosecution proceeding and therefore does not have legal standing to appeal. Furthermore, the IMPI does not issue a formal resolution to the opposition itself.

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 Civil Courts. There is concurrent jurisdiction for both Federal and Local Civil Courts and its resolution as to ownership must be complied with by the IMPI.

However, a cause of invalidity is provided both in the MIPL and IPPL when a patent was granted to a person/entity that was not entitled to apply for it.

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

The IPPL contemplates a one-year grace period. This one-year grace period is limited in the MIPL to public disclosures made by applicants or inventors. However, in the IPPL, the grace period applies more broadly to any direct or indirect public disclosures made by the inventor(s) or applicant(s), or by third parties that obtained the information from them.

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 subject to the grace period.

5.7 What is the term of a patent?

The term of a patent is 20 years from the filing date. Term extensions are available in Mexico; please see question 4.1 above.

5.8 Is double patenting allowed?

Double patenting is not allowed in Mexico.

5.9 For jurisdictions within the European Union: Once the Unified Patent Court Agreement enters into force, will a Unitary Patent, on grant, take effect in your jurisdiction?

This is not applicable to our jurisdiction.

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?

Injunctions are available for any infringement of patent rights on a provisional and permanent basis in Mexico. The Customs Law establishes the rules for implementing the same with Mexican Customs. Mexican Customs have the faculty to retain

a product for Intellectual Property matters for a limited period of five days, but if no action is executed by third parties, the importation process will continue, thus it is necessary to have an official order from the competent authority, indicating that an administrative action was submitted. Once Customs receive the evidence that an injunction request was filed, the products will be seized.

For the implementation of the preliminary injunctions, it is necessary to submit the petition and the IMPI will analyse the appearance of a *prima facie* case and the non-violation of public order provisions. The IMPI will also take into consideration the seriousness of the infringement and the nature of the preliminary injunction. For such analysis, the party moving forward with the injunction must prove the requirements mentioned in question 1.23.

In the case of importations, there are two cases: the product was imported to enter the Mexican market; or the importation was a transshipment.

For both cases, preliminary injunctions are available on an *ex parte* basis. However, after the defendant is served with the injunctions, the alleged infringer is entitled to the lifting of preliminary injunctions by placing a counterbond, in which case the MTO will analyse if the damages that the alleged infringer may suffer with the implementation of the injunctions are greater than the damages that the plaintiff may suffer. 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.

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/or the seizure of the infringing goods.

If the product was imported as a transshipment, the first notification to the infringer must be done according with the legal requisites for foreign notifications. This procedure is commonly conducted through the Ministry of Foreign Affairs.

With regard to the time frame, once the legal requisites are fulfilled, preliminary injunctions are adopted and put into practice in a rather fast fashion that may range from two to seven days, depending on the urgency of the implementation; 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.

On July 20, 2016, the Mexican Antitrust Commission (known by its Spanish acronym, *COFECE*) announced that it will conduct a study regarding competition concerns over pharmaceutical products with lapsed patents. This is the first time such a study has been undertaken in Mexico.

The Commission will first analyse the rationale behind the fact that there are approximately 350 products listed in the National Formulary with sole suppliers, although around 63% of these products have lapsed patents. The *COFECE* emphasised that this analysis should not be considered in any way a prejudgment of potential misconducts. It pointed out that this assessment aims to provide Mexican regulatory agencies with recommendations on how to encourage competition and correct inefficiencies.

We believe that the *COFECE* official communication in this regard contains several flaws and confuses concepts in order to justify the study. For example, the Commission provides data concerning out-of-pocket expenses of the private sector to explain its reasoning for reviewing public acquisitions of medical products; however, these are separate realms governed by various factors and rules and are not necessarily related.

7.3 In cases involving standard essential patents, are technical trials on patent validity and infringement heard separately from proceedings relating to the assessment of fair reasonable and non-discriminatory (FRAND) licences? Do courts set FRAND terms (or would they do so in principle)? Do courts grant FRAND injunctions, i.e. final injunctions against patent infringement unless and until defendants enter into a FRAND licence?

Yes. The technical trials on patent validity and infringement are heard by the IMPI, whereas proceedings relating to the assessment of FRAND licences are heard by the *COFECE*.

There is no precedent in which FRAND injunctions were granted against patent infringement. However, the *COFECE* has broad faculties to impose injunctions; thus, it may be argued that such authority could order the stay of a patent infringement case until a proceeding concerning a FRAND licence is decided, or even a final injunction against a patent infringement.

8 Current Developments

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

The main developments that were expected that are now a reality include the introduction of the USMCA, and the IPPL which entered into force on November 5, 2020.

In regard to patent prosecution and patent litigation, the IPPL contains significant developments which are mentioned above and can be summarised as follows:

- Double patenting prohibition. While this is the current practice, the new practice will introduce an explicit prohibition.
- A grace period for prior disclosures made by third parties in violation or breach of confidential agreements.

- A new legal system for divisional patents that will narrow the possibilities for patent owners to divide their parent application multiple times.
- A new “Bolar” clause for biotechnological and chemical inventions.
- Supplementary Patent Certificates to compensate for the delay in granting the approvals of marketing authorisations.
- Prohibition for narrowing the scope of the allowed claims when an invalidity action has started.
- Authority to allow monetary damages after the infringement ruling is granted to the IMPI. In such case, the IMPI will open an incidental proceeding to rule on this matter.
- Direct jurisdiction to Civil Courts, both Federal and Local, to rule on damages.
- The 40% rule, as described in question 1.24 above, remains in place.
- A new conciliation proceeding before the IMPI has been introduced.
- A new Parallel Patent Grant agreement between the United States Patent and Trademark Office and the IMPI.

Likewise, in 2020, Mexico joined the Hague System related to Industrial Designs, and so now applicants can use the Hague System to protect their industrial designs in Mexico. Besides allowing foreign applicants to protect their designs in Mexico through this system, Mexico’s accession would also allow Mexican companies and designers to seek protection in contracting parties of the 1999 Act of the Hague Agreement by means of a single international application. It is important to bear in mind that: Mexico does not allow deferment of publication; a design application must refer to a single design or a group of designs so linked as to form a single design concept so the division of the application may be requested during the examination; and that the maximum duration of protection for designs is 25 years.

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

New regulations for the IPPL were expected in 2022; however, it is expected that in the last quarter of 2023, or 2024, the regulations will be issued. Regulations cannot exceed the general legal framework provided by law, and therefore, no substantial changes are expected; rather, specific provisions on how to apply the law are expected.

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

Over the past few years it has been a trend to file *ex parte* post-grant amendments to patents when invalidity actions were filed against them; however, this possibility is forbidden in the IPPL.

On the other hand, use of the new civil venue for collecting damages for IP violations, including patent violations, will certainly be a trend in the coming years.



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Mr. Sánchez's work is extensive, with experience in prosecution and litigation across all areas of IP, including trademarks, copyrights, patents and unfair competition. His broad background allows him to tailor enforcement strategies to a range of needs. His practice is focused in litigation and regulatory matters, with a specialisation in life sciences and technology. Mr. Sánchez co-chairs OLIVARES' Litigation Team, the Patent Team and the IT industry group. His team is focused on litigation before the Mexican Institute of Industrial Property (IMPI) and the Federal Courts and in patent prosecution before the IMPI. As one of the few regulatory and administrative litigation experts in Mexico, Mr. Sánchez guided the development and implementation of a revolutionary and proprietary software system that replicates the drug-naming and labelling approval process within COFEPRIS, Mexico's health ministry.

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Rommy Morales boasts over 16 years of experience in IP, with a specialisation in patent prosecution, IP litigation, and plant variety protection. She is renowned for accurately identifying clients' needs and subsequently developing and implementing strategies tailored for the protection of their industrial property rights. Ms. Morales provides technical and legal advice to national and international clients in the pharmaceutical, biotechnology, and chemical industries. Her advice covers the preparation, filing, prosecution, granting, and enforcement of patents, including patentability and validity opinions, as well as freedom-to-operate analyses.

In her role, Ms. Morales supervises the team responsible for filing and prosecuting patent applications. Owing to her distinguished reputation as a biologist and her extensive experience in the field, she also leads the department dedicated to plant variety protection in Mexico. Ms. Morales has participated in numerous legal proceedings related to life sciences, including litigation cases involving pharmaceutical products of significant commercial interest.

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OLIVARES began in 1969 as an IP 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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