THE PATENT LITIGATION LAW REVIEW

Third Edition

Editor
Trevor Cook

THE LAWREVIEWS

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CONTENTS

PREFACE

Although patent litigators should always be mindful that patent litigation has, with some justification, been called the 'pathology of the patent system', not so much as a criticism, but more in recognition of how remarkably little patent litigation there is, in fact, when seen in relation to the ever increasing number of patents in force at any one time, patent litigation is also the anvil on which patent law is forged. This is because the 'black letter' law of patents tends to be terse by comparison to most other areas of law, and it is only with experience of how courts and tribunals interpret such law and apply it that one can start to appreciate its true scope and effect. This, in part, explains how such similarly expressed statutory provisions as one finds in different patent laws can sometimes result in such different outcomes in different jurisdictions – disparities that are all the more evident when they concern the same product or process, and patents that, though in different jurisdictions, are all members of the same family, and are all intended to protect the same invention. As it becomes increasingly common for patent disputes to proceed in multiple jurisdictions these differences in outcome become ever more apparent.

Such disparities are not only a consequence of differing substantive laws, or differences in interpretation of similarly expressed laws. They can also be a consequence of the considerable procedural differences between jurisdictions, the nature of which is outlined in this Review. However, the Review does not only summarise patent litigation procedures. The respective contributors to it, as leading practitioners in each of their jurisdictions, also focus on recent developments in substantive patent law as demonstrated by the most important recent court decisions in their respective jurisdictions, meaning that this Review also provides insight into the current controversies that affect patent law generally.

On a global basis courts in multiple jurisdictions continue to be involved in controversies over standard-essential patents, one emerging aspect of which is the potential challenge that these present to the territorial nature of patents, as exemplified by the appeal, to be heard by the UK Supreme Court this autumn, against the imposition by the English courts of a global licence, on terms that they assess, as the price for exploiting standard-essential patents in the UK. Meanwhile, three appeals concerning standard-essential patents are pending before the German Federal Supreme Court, providing it with its first opportunity for a decade (since its Orange Book Standard decision) to revisit this area of the law. In the United States the most prominent controversy remains the question of excluded subject matter, which for want of clear judicial guidance has now attracted the interest of the legislature. In Europe, one apparent trend is towards greater flexibility as to injunctive relief, particularly in medicine – by for example, in the UK, tailored injunctions, or, in Germany, expedients such as compulsory licences, although in Germany there is also talk of legislation to address the issue. Again in Europe, the past year has seen no progress towards the entry into force of the

long-heralded Unified Patent Court Agreement. Although the pending challenge before the Federal German Constitutional Court to the consistency of the Agreement with the German Constitution is the only formal impediment to its entry into force, the imminent withdrawal of the UK from the EU as from 31 October 2019 presents a further problem, because the Agreement as drafted does not envisage participation by non-EU Member States. This raises the prospect, even if the German challenge is rejected, of having to amend the Agreement before it can enter into force to take account of such withdrawal; either to exclude the UK from its scope or, as the UK government has urged, expressly to provide for its inclusion, a course that, however, it is not at all clear would be compatible with the case law of the European Court of Justice, irrespective of any treaty language.

Trevor Cook
Wilmer Cutler Pickering Hale and Dorr LLP
New York
October 2019

Chapter 15

MEXICO

Armando Arenas Reyes, Luz Elena Elías and Erwin Cruz[1]

I OVERVIEW

Mexico is one of the leading countries in Latin America, and has an increasing amount of patent litigation. The Mexican market is important for many multinational organisations because it has an estimated gross domestic product of around US$2.224 trillion.

Patent litigation is handled at first stage by the Mexican Institute of Industrial Property (IMPI), which is also in charge of granting patents. The appeal stage before the Federal Court for Administrative Affairs is handled by a specialised bench on intellectual property (IP) matters. The judges only handle IP matters, but they do not need to have technical backgrounds. Circuit courts handle the final appeal stage.

Most patent litigation is related to pharmaceutical products and, recently, biotech products. The Mexican Industrial Property Law (IP Law) is pro-patents, as are the IMPI and courts. Generic efforts are usually against the patent system; fortunately, they have not had a strong influence.

Patent litigation is supposed to be an abbreviated process, but in practice it is a lengthy process as a result of Mexico's civil law system. Strong expertise and key evidence is needed to reach a positive outcome. Damages can be pursed after reaching an infringement ruling beyond the appeal stage. Recently, few patent infringement cases have reached that point. Patent case law is still under construction in Mexico.

II TYPES OF PATENT

Products and processes can be the subject of patent protection under the IP Law and its regulations, provided that they meet patentability standards – mainly novelty, inventiveness and utility.

Utility models are also the subject of protection under the IP Law, provided that they meet novelty and utility standards.

The IMPI grants patent protection. Where pharmaceutical products, compounds are concerned, formulations, uses and manufacturing processes of medicines are the subject of patent protection.

Article 19 of the IP Law excludes medical procedures from being the subject matter of an invention. However, a patent can be obtained for a therapeutic method by drafting the claims in the EPC2000 or Swiss-style format.

1 Armando Arenas Reyes is a partner and Luz Elena Elías and Erwin Cruz are attorneys at Olivares.

i Obtaining protection

Applications must be filed before the IMPI. The average time for obtaining a Mexican patent varies, depending on the field of technology. Generally, it takes from three to six years to obtain a patent.

The IMPI conducts a formal examination of the documentation and may order clarifications or further details, or that an omission be remedied. If so, an official communication requests the outstanding documents (that is, a power of attorney and an assignment of rights). This communication is usually issued four to six months after filing.

The abstract is published in the Official Gazette. This step normally occurs 18 months after the filing of the priority claim or, if no priority is claimed, 18 months from the filing date.

Examination on the merits of the invention begins automatically after the corresponding fees are paid, concurrent with filing the application.

An official action is issued between two and three years after the filing date either requesting amendments to the claims (for example, due to disapproval or clarification regarding novelty), or granting the protection sought and requesting payment of the final IMPI fees together with the payment of the first five annuities.

Maintenance fees are due every five years until the end of the patent term.

ii Patent Prosecution Highway programmes

The IMPI has implemented Patent Prosecution Highway (PPH) pilot programmes to accept examinations by foreign patent offices, such as the United States Patent and Trademark Office, the European Patent Office, the Japanese Patent Office, the National Intellectual Property Administration of China, Pacific Alliance (Colombia, Chile and Peru), the Spain Patent Office, the Singapore Patent Office, the Canada Patent Office, the Portugal Office, the Austria Patent Office and the Korean Intellectual Property Office. In general, PPH is a mechanism that enables applicants to request accelerated substantive examination, based on the search and examination results from an office of first filing, who have already determined one or more claims to be allowable.

The request for examination under PPH should be filed after the publication of the patent application in the Industrial Property Gazette and prior to the issuance of the first official action.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

The only venue to enforce and to contest validity of a patent is through administrative proceedings (an infringement action or an invalidity action) before the IMPI. The IMPI is an administrative authority that has exclusive jurisdiction to hear all patent infringement and invalidity cases at first stage. There is no judge or jury participation in patent infringement actions.

i Evidence

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

The IP Law does not regulate the manner in which an invalidity or infringement is to be proven. The Federal Code of Civil Procedure is applied supplementary to the IP Law.

Expert testimony can be filed as documentary evidence or as a report given during the proceeding. The IMPI also requires a technical report from its Patents Department to determine the grounds of an invalidity or infringement action.

The IMPI rejects depositions and testimonial evidence unless they are included with an affidavit. Affidavits will not be considered a primary source of evidence. Mexican law does not allow live testimony or cross-examination of witnesses. However, in accordance with recent case law issued by the federal courts, IMPI has been ordered to admit this evidence for isolated cases. Actually, it is under discussion as a part of draft of the reform to the IP Law to permit this type of evidence.

ii Obtaining evidence from defendant and third parties

In Mexico, there is no pretrial stage or discovery. However, the plaintiff in an infringement action is entitled to request from the defendant all the documentation necessary to help to prove the infringement that should be in the defendant's possession. The plaintiff must request from the IMPI the issuance of an order addressed to the defendant requesting this documentation and data, pointing out exactly what documents he or she is pursuing, and the importance and relevance of them to the prosecution of the infringement case. In case of lack of compliance with this order, a fine will be imposed on the defendant and the facts that plaintiff were seeking to prove with the documentation requested will be considered proved.

iii Structure of the main proceeding

Basically, the Mexican enforcement of a patent starts with an infringement claim filed before the IMPI. The claim is served on the alleged infringer, who then has 10 working days to respond and, if applicable, bring a counterclaim. That response is then served on the claimant to refute it. All the evidence is analysed, and finally a decision is issued.

At first sight, the proceeding seems abbreviated. In practice, depending on the evidence submitted by parties and the backlog at the IMPI, the proceeding becomes lengthy. A decision by the IMPI usually takes between 18 and 24 months. However, there are cases where the decision has taken up to five years.

iv Defences

An accused infringer may assert that the patent that is the subject matter of the infringement action is void, and hence subject to nullity.

This defence should be alleged when answering the plaintiff's claim, but by means of a counterclaim. The IMPI will give notification of the counterclaim to the party that filed the original complaint. In practice, both the infringement claim and the counterclaim are decided simultaneously to preclude the possibility of contradictory resolutions. Conversely, the IP Law is silent in this regard and establishes that invalidity challenges provide a basis for staying proceedings for infringement.

For our comments on invalidity and other defences, please see Section IV.iii.

v Preliminary injunctions

The provisional injunctions established by the IP Law are essentially:

a ordering the recall or impeding circulation of the infringing merchandise;

b ordering the following materials to be withdrawn from circulation:

- illegally manufactured or used articles;

- articles, packaging, wrapping, stationery, advertising material and other similar items that infringe upon any of the rights protected by law;
- advertisements, signs, posters, stationery and other similar articles that infringe any of the rights protected by law; and
- utensils or instruments destined for or used in the manufacture, production or obtainment of any of the concepts indicated in the above bullet points;

c immediately prohibiting the marketing or use of the products with which any rights protected by the law are violated;

d ordering the attachment of the commodities of the products (pursuant to Articles 211–212 *bis* (2) of the IP Law);

e ordering the alleged transgressor or third parties to suspend or cease all acts that constitute a violation to the provisions of the law; and

f ordering a suspension of service or the closure of the establishment when the measures indicated above are insufficient to prevent or avoid the violation of rights protected by the law.

The same obligation is imposed on producers, manufacturers, importers and their distributors, who will be responsible for immediately recalling the products that are found in trade.

vi Requirements for getting preliminary injunctions

In order to grant preliminary injunctions, the IMPI requires the petitioner to comply with the following:

a provide evidence showing that he or she is the holder of the right, proving any one of the following hypotheses:
- the existence of a violation of his or her right;
- that the violation of his or her right is imminent;
- the existence of the possibility of suffering an irreparable damage; and
- the existence of a grounded fear that the evidence may be destroyed, concealed, lost or altered;

b post a bond in a sufficient amount to respond to harm and damages that may be caused to the person against whom the measure has been requested. (The main problem with this is that the law and regulations are silent about the rules and parameters for the IMPI to fix the amount of the bonds and eventual counterbonds to lift the preliminary injunctions.) (The full discretion of the IMPI in this regard has caused certain inequities that have provoked the continuation of the infringing activity rather than discouraging the infringer due to the contingency); and

c provide necessary information to identify the products, services or establishments with which or where the violation of industrial property rights is committed.

The IMPI will take into account the seriousness of the infringement and the nature of the requested measure to determine the amount of the bond and the counter-bond.

vii Structure of the preliminary injunctions proceeding

If a plaintiff chooses to ask the IMPI for a preliminary injunction, a bond will be fixed to warrant possible damages to the defendant. This injunction should be petitioned in writing, and within a term of 20 days from its execution the plaintiff is required to file a formal written claim of infringement. Failure to do so will cause the plaintiff to lose the bond in favour of the defendant.

Once the injunctions are imposed, the IMPI may request to broaden the amount of the bond, if necessary. The main problem with setting this amount is that the law and the regulations are silent about the rules and parameters for the IMPI to fix such amounts. The IMPI's faculty of discretion in this regard has caused certain inequities that have also caused the continuance of the infringing activity rather than discouraging infringers.

Injunctions must be requested by means of a writ. The defendant has the right to place a counter-bond to stop the effects of the provisional injunction, which amount will have to be 40 per cent higher than the amount of the bond posted by the plaintiff. Defendants have the right to allege whatever they deem pertinent with respect to the provisional injunctions within a term of 10 days from the date of execution.

viii Costs

IMPI fees are very low, and there are no government fees for appeals before the courts.

ix Invalidity actions and post-grant amendments

The IP Law states that amendments or changes in the text or drawings of a letter patent may be allowed only to correct any obvious or formal errors, or to narrow the scope of the claims. The IP Law is silent about post-grant amendments for those patents under litigation, and there are few court precedents in this regard to rely on.

Olivares has pioneered a method of handling cases where a post-grant amendment petition is submitted as a strategy in response to an invalidity action. This strategy has achieved positive outcomes, but those cases wherein the strategy has been implemented are pending decisions on the merits of the cases and have not reached final decisions yet.

IV SUBSTANTIVE LAW

i Infringement

The IP Law grants patentees the right to the exclusive exploitation of the patented invention. Therefore, a patent grants the right to exclude others from making, using, offering for sale or importing the patented invention.

The IP Law sets forth, essentially, that the following acts are causes of patent infringement:

a manufacturing or producing products covered by a patent without the consent of the holder or without the respective licence;

b offering for sale or placing into circulation products covered by a patent, knowing that they were manufactured or produced without the consent of the patent holder or without the respective licence;

c using patented processes without the consent of the patent holder or without the respective licence; and

d offering for sale or placing into circulation products that are the result of putting into practice patented processes, knowing that they were put into practice without the consent of the patent holder or the person who had a licence for their working.

The IP Law establishes direct infringement over the manufacturer. Infringement against sellers requires evidence of prior notice of the alleged infringement.

When a plaintiff claims infringement of a patented process, the defendant has the burden of proving the use of a different process other than the patented process.

The IP Law recognises literal infringement. The IP Law does not directly establish contributory infringement, but some cases for inducing infringement are under test.

ii Standard

The IP Law is silent on the matter of a statute of limitations. Thus, the patentee may bring a patent infringement suit with the IMPI at any time while the patent is in force.

The plaintiff must prove that the wording of the patent's claim or claims cover the alleged infringing product or process. First, the plaintiff must define the scope of the approved claims. The IP Law provides that the span of the claims is determined by its wording, aided by the description and drawings.

The interpretation of the claims and the use of the patented invention on the infringing product or process are technical issues. Therefore, infringement actions usually require expert evidence even though a technical report from the Patents Department may be rendered by a request from the Contentious Department, which handles IP litigation, both of the IMPI.

iii Invalidity and other defences

Invalidity action

The IP law establishes several grounds upon which a patent can be invalidated:

a when the patent was granted in contravention of the provisions on requirements and conditions for the grant of patents, Articles 16, 19, 27, 31 and 47 of the IP Law, which essentially include:
- lack of novelty (anticipation, prior public use, prior sale and prior disclosure);
- lack of inventive step;
- lack of industrial applicability;
- non-patentable subject matter;
- lack of clarity (indefiniteness);
- unsupported claims (added subject matter); and
- non-enablement;

b when the patent was granted in contravention of the provisions of the law in force at the time when granting. Actions based on this cause of invalidity cannot challenge the legal representation of the applicant when prosecuting and obtaining a patent;

c when the patent application was abandoned while prosecuted; and

d when the patent is granted by error or serious oversight, or when it is granted to someone not entitled to obtain it (ownership errors and inventorship errors).

The Contentious Department has issued some decisions allowing arguments against claims to priority inserted into grounds of invalidity of lack of novelty or inventiveness. However, such decisions are under appeal.

Other defences

A prior use defence would be also available as a cause for non-infringement. Additionally, the Mexican patent system operates on a first-to-file basis.

No laches defence is recognised by the IP Law.

The usual exceptions by importers are experimental use and *Roche-Bolar* exceptions; however, neither of them apply to commercial activities and such activities that will eventually end in the commercialisation of the generics would be considered commercial.

The experimental use defence

This is established in the IP Law, Article 22(I). Although the terms and conditions for this exception are not expressly detailed in the law, it is considered as the use of a patented invention for pure experimental and non-commercial purposes. The burden of the proof of the experimental use is on the defendant.

The Roche-Bolar exception

It is established in the Linkage Regulations, which in general terms state that during the three years before the expiration date of the patent related to chemical APIs, and the eight years before the expiration of the patent related to biologic APIs, anyone can use the patented product only for the purposes to obtain the corresponding marketing authorisation. The marketing authorisation, however, will be granted after the corresponding patent expires.

Currently, there is no jurisprudence or binding decisions regarding the parameters over these two exceptions, and they are still the subject of debate before the Courts.

Conversely, Olivares have handled the enforcement of patents against the importation of patented APIs that exceeded amounts for experimental use or *Roche-Bolar* exceptions with great success against infringing manufacturers and brokers. For example, we have obtained decisions stating that broker companies importing patented APIs were subject of infringement because their activities did not qualify for the *Roche-Bolar* exception.

Standard

Patent invalidity decisions are relatively difficult to obtain. The plaintiff must prove that the invalidity cause occurred. These actions usually require conclusive evidence even though a technical report from the Patent Department may be rendered by request of the Contentious Department, both of the IMPI.

V FINAL REMEDIES FOR INFRINGEMENT

i Sanctions

Several administrative sanctions can be imposed on a person found to have infringed a patent, ranging from a fine of up to 20,000 units (approximately US$105,000) to a definitive closure of the establishment (Article 214, IP Law). Repeated infringement activity is also considered a criminal offence (Article 223, IP Law).

ii Damages

The affected party may bring an additional claim for damages and lost profit in a civil law action. Damages and lost profits start accruing from the date on which the existence of an infringement can be proven.

Likewise, the IP provides a rule, applicable in all type of patent, trademark and copyright infringement actions, imposing on the civil courts the obligation to declare monetary damages of at least a 40 per cent of the commercial value of the infringing products. This minimum standard provision is known as the 40 per cent rule.

For cases related to trademarks and patents, the civil action can be claimed once the decision regarding the infringement is final; for copyright the civil action can be claimed at any time.

Recently, the Mexican Supreme Court issued a non-binding decision establishing that getting a final IP infringement decision does not meant the IP rightholder automatically suffered damages. Thus, IP rightholder should demonstrate actual damages. We observe this decision has some flaws in its reasoning and, fortunately, it is non-binding. There will be other cases to properly address why an IP right infringement directly causes collectable damages and why the 40 per cent rule should directly apply.

Attorney fees are very hard to obtain, and in any event, would be discretional to the judge. The civil laws do recognise attorney fees, but without expressly stating how judges can make them applicable.

A civil action claiming damages must be filed within two years of the infringing ruling being ineligible for appeal.

First ruling in Mexico awarding patent holder with damages higher than the 40 per cent rule

Olivares devised an action that allowed a patent holder of a blockbuster product to collect close to 63 per cent of sales of infringing products.

A generic company achieved two marketing authorisations to sell a pharmaceutical product with a patented compound while the patent was in force. Further to patent infringement actions, the patent holder pursued actions against the generic's marketing authorisations. These actions ended before the District Courts, which granted the generic with injunctions to keep such marketing authorisations in force while the court actions were pending of a final decision as to the merits.

The patent holder was able to revert to the granted injunctions and to reach a final decision before the Circuit Courts invalidated the generic's marketing authorisation. Conversely, during the few weeks that such injunctions were in force the generic gained several million peso's worth of sales.

Through innovative actions before the District Courts, the patent holder claimed damages and lost profits from the generic's sales under injunctions. Among other damages, the patent holder claimed its exclusive right to receive all sales of pharmaceutical products with the patented compound. It also claimed lost profits derived from the fact that the infringing products were sold under patentee's product prices. The plaintiff had to submit proof of experts to demonstrate the amount of sales. The generic used this chance to argue costs such as manufacturing should be discounted. After years of litigation, the patent holder reached a final decision awarding it around 55 per cent of claimed sales (which is, of course, higher than the 40 per cent provided by the IP Law).

In view of the generic's reluctance to pay, the patent holder had to additionally pursue a civil action to execute the awarding ruling. After further years of litigation, the patent holder was awarded not only around 55 per cent of generic's sales, but also an additional 17 per cent of main claimed amount as interests and legal expenses. The patent holder had a high burden

of effort and time, but prevailed and collected close to 63 per cent of generic's sales at the end. No other case like this has been litigated in Mexico before, even after the Supreme Court's non-binding ruling commented above.

We consider this case provides patent holders with a clear vision over those challenges involved in collecting damages from infringers, taking advantage of expertise that is beyond that of the case recently decided by the Supreme Court.

VI OTHER TYPES OF PATENT PROCEEDING

i Linkage regulations

Pursuant to Article 167 *bis* of the Health Law Regulations, on filing the application, the applicant has to prove that he or she is the owner or licensee of the patent of the active ingredient of the product (recorded before the IMPI), or state under oath that their application does not violate the list of products published in the Linkage Gazette, and observes patent law.

Before granting a marketing authorisation to third parties other than the patent holder, the Mexican Healthcare Products Regulatory Agency (COFEPRIS) must check the listed patents, first by compound and then by the list of patented products issued by the IMPI in the *Linkage Gazette*, which is organised according to the active ingredient's generic name. Therefore, COFEPRIS and the IMPI have the burden of analysing whether an MA application invades a listed patent.

As mentioned, COFEPRIS may request additional information from the MA applicant. If COFEPRIS suspects that patent rights may be violated, it can request technical assistance from the IMPI regarding the scope of third patent rights.

If COFEPRIS requests technical assistance, the IMPI then has 10 days to produce an opinion on the scope of the patent and whether the product for which MA is sought falls within patent protection.

If the IMPI is of the opinion that the product in question falls within the scope of a published patent, in practice, COFEPRIS may give the applicant the opportunity to show that it has a right to make and sell that product.

If an applicant does not convince COFEPRIS, the application may either be suspended until the expiration date of the patent, or rejected. In the first scenario, the application may stay in abeyance until the patent term expires if this was filed three years prior to such term for chemical products, and eight years for biotechnological products, under the *Roche-Bolar* exception.

VII APPEAL

A decision by the IMPI can be appealed either before the IMPI through a review recourse within a term of 15 working days, or before a specialised IP section of the Federal Court for Administrative Affairs (FCAA) within a term of 30 working days.

Review recourses usually take around seven to 10 months for decision, which can be further appealed before the FCAA.

Appeals before the FCAA usually take around 12 to 15 months. A final stage of appeal before a Federal Circuit Court usually takes between six and 10 months.

In Mexico City, there are 20 federal circuit courts to deal with administrative matters; however, each case is chosen randomly by a computer system. By territorial jurisdiction, IP matters are mainly decided in Mexico City.

VIII THE YEAR IN REVIEW

i First final ruling about post-grant amendments related to a patent invalidity action

A Federal Circuit Court ordered approval of post-grant amendments of a patent under invalidity action for the first time ever in Mexico.

In 2015, a generic company filed an invalidity action against a formulation patent before the IMPI, arguing, among other issues, that the claimed scope was broad and without support on patent specification. In reply to the invalidity action, the patentee filed a post-grant amendments petition narrowing the scope of their claims, which is an innovative action in Mexico because the IP Law is silent about post-grant amendments for those patents under litigation and there were no court precedents in this regard to rely on. Moreover, the IMPI usually invalidates patent claims rather than narrowing their scope.

While the invalidity action was ongoing, the IMPI refused the post-grant amendments petition alleging they were against the essence of the invention. The patentee appealed this decision before a higher rank officer than the one that issued such refusal, but were again refused the amendments, stating this time that by eliminating claims the patentee was broadening the scope of the patent rather than narrowing it.

Tbe patentee had to appeal such refusal before the Federal Court for Administrative Affairs. Importantly, in this stage, the patentee filed an injunction ordering the IMPI to avoid any act that may impact the letter's patent while the appeal is decided in the merits. Moreover, the generic company attempted to allege the amendments refusal should be upheld, without success. The Court reversed the amendments' refusal in part but not in full. Therefore, the patentee had to appeal such reversal before the Circuit Court to reach a full reversal.

After almost four years of litigation, the Circuit Court reversed the amendments rejection, ordering the IMPI to approve the amendments petition in full. The Circuit Court established that the patentee was allowed to amend its patent and that eliminating claims does not broaden the scope of the patent. They found such elimination reduced the subject matter protected by this patent.

This ruling is final and it is pending compliance. Although it is not binding for other cases, the ruling provides a way for patentees to redefine and narrow the scope of their patents under invalidity actions in Mexico. To prevent this, the IMPI tries to invalidate them under improper assessments, since they usually invalidate claims rather than narrowing their scope.

ii IP owners may be awarded with more than the minimum rule of 40 per cent of infringing products' sales

A Circuit Court recently observed that industrial property owners can be awarded with actual damages plus 40 per cent of infringing products sales as punitive damages.

The Mexican IP Law, Article 221 *bis*, provides that damages awarded to the claimant shall be no less than 40 per cent of the sales of the infringing product at the price of sale to consumers (the 40 per cent rule).

The Mexican Supreme Court essentially ruled that to be entitled to damages, further to demonstrating an IP infringement beyond shadow of appeal, claimants must demonstrate suffered harm and a causal nexus between the IP infringement and such suffered harm.

Based on an analysis of punitive damages in the US legal system, the Circuit Court reasoned that the 40 per cent rule seems to apply the principle of punitive damages in the Mexican legal framework. Therefore, the Circuit Court commented that judges can impose both compensatory damages for loss suffered, provided that the requirements established by the Supreme Court are met, and the 40 per cent rule as punitive damages.

At first sight, this may seem like a more favourable interpretation of the IP Law for claimants. Conversely, the text of the ruling is ambiguous, and the proposed interpretation of the Law may mean that the court has unlimited discretion to determine the amount of compensatory damages, further to imposing the 40 per cent rule.

According to the Mexican legal system, this Circuit Court precedent is not binding and, thus, we consider that the application of the 40 per cent rule continues. This reassures any claimant that it is guaranteed to this minimum, as long as it meets the test above. Nonetheless, extensive expertise to claim damages in Mexico is always advisable, since navigating the rules and venues to claim damages derived from the violation of IP rights in Mexico has been a problem for many years.

In light of this decision and the recent approval of the USMCA that provides minimum standards to claim damages, we consider that the IP Law requires urgent amendments to provide better guidelines, including the definition, nature, origin and types of damages that can be claimed and recovered and the methods for doing so. This is to avoid loose interpretations by the courts, which would require lengthy and strenuous civil litigation to be contested.

IX OUTLOOK

i New Health Law Proposal Would Limit Mexican Patent Linkage System

Mexico's Senate published in its official gazette a proposal to modify the Mexican Health Law to reduce the scope of the linkage system with respect to certain pharmaceutical patents.

In summary, the proposal includes the following changes to the linkage system:

a An applicant for an innovative drug must post a copy of the patent covering the active ingredient of the medicine to be approved with COFEPRIS and prove that the applicant is the owner or licensee of said patent.

b COFEPRIS will integrate and publish a list of approved innovative products, citing only one patent per product covering the active ingredient and its expiration date.

c Only one patent can be listed for each innovative chemical synthesis drug.

d If the patent is granted after the authorisation of the innovative drug, it should be included in the list issued by COFEPRIS no later than one month after issuance of the patent.

e The generic applicant must include a statement under oath that the sanitary registration of a generic medicine does not infringe the active ingredient patent rights along with a corresponding analysis of why it does not infringe.

f The generic applicant can request that generic registration is granted immediately after the expiration of the active ingredient patent term related with the innovative drug.

g The information provided by the applicant for a generic marketing authorisation to COFEPRIS should be sent to the IMPI for an analysis limited to the active ingredient patent related to the product; the IMPI should provide a response to COFEPRIS within a term of 10 working days. If the IMPI does not respond within that time period, the generic application is assumed to have a green light to proceed, and COFEPRIS can authorise the generic product.

h Patents for biologics will not be considered.

i Generally, the Health Law proposal contradicts what is established in Article 28 of the Constitution and other articles of the Industrial Property Law, which recognise exclusive rights for all inventions, without creating exceptions for certain categories.

The proposal disregards the jurisprudence of the Mexican Supreme Court, which, after many years of discrimination against formulation patents, ruled that formulation patents should be part of the patent linkage system.

The legislative proposal also contradicts definitions provided by the Health Law itself and international treaties, such as the text of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, which establishes a linkage system contemplating protection of patents for approved pharmaceutical products. It would also violate the US-Mexico-Canada Agreement (USMCA), which calls for a linkage system without discrimination, including for patents covering pharmaceutical products.

The IMPI does not welcome this proposal and it seems that it does not have much acceptance within legislators. Olivares is closely following it.

ii Proposal to Modify IP Law to Empower IMPI

Mexico's Senate recently published in its Official Gazette a proposal to modify several provisions of the Mexican Industrial Property Law (IP Law). In summary, the proposal includes the following additions to the IP Law:

a The IMPI, as the administrative authority in IP matters, would be empowered to carry out the following actions:

b The IMPI may seize goods to be imported, exported, or that are in transit, in accordance with the Customs Law.

c The Office may issue decisions, including compensation for damages, caused by the violation of IP rights.

Currently, a claim of damages derived from a finding of infringement of a patent or trademark can be initiated only in a civil court, and only once the decision issued in the administrative infringement action is final beyond the shadow of appeal.

There is no doubt that it is necessary to improve the enforcement system in Mexico by avoiding multiple independent and consecutive proceedings to obtain an award of damages.

However, the proposal may be questionable because under the Mexican Constitution, administrative authorities such as the IMPI arguably cannot determine awards nor enforce damages, as the IMPI is not considered a court of law.

If the purpose of this proposal is to provide the IMPI with the ability to award damages, other bodies of law should be modified as well.

It is our view that Mexico's IP enforcement system should be reviewed in its entirety, and the power to decide IP conflicts trusted to certain established courts of law. Under this system, a single proceeding could result in a ruling on infringement and any applicable damages award.

Appendix 1

ABOUT THE AUTHORS

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Armando Arenas is a partner. His areas of practice are pharmaceutical law, IP litigation and enforcement. He has detailed regulatory expertise regarding health law, and provides strategic advice in complex patent litigations cases and dispute resolutions. Armando's clients and deal experience include all segments of the industry – pharma, biotech, medtech, diagnostics, animal health, vaccines and health services. He also represents life sciences companies before the Mexican courts, and has handled the following relevant cases:

a restoration of a patent's life term granted under provisions of Article 12 transitional (pipeline patents);

b infringement actions of patents covering pharmaceutical products declared final and beyond appeal against generics companies;

c the first case in Mexico where it was resolved that the revocation of the marketing authorisation of a pharmaceutical product was in violation of a formulation patent listed in the Linkage Gazette;

d the first case in Mexico of a use patent being effectively enforced in Mexico related to public tender;

e the unconstitutionality of Article 167 *bis* of the Health Supplies Regulation, as it does not provide the right of the titleholder of a patent to be heard during the prosecution of the marketing authorisation; and

f the first case in Mexico enforcing the linkage system in order that the local regulatory agency consider a use patent included in the Linkage Gazette for allopathic medicines.

Armando has a bachelor's degree from the National Autonomous University of Mexico (1995). His languages are English and Spanish.

LUZ ELENA ELÍAS

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Luz Elena Elías studied law at the National Autonomous University of Mexico (1994). She has an LLM degree from the University of Ottawa in Canada, and a master's degree in patents, trademarks and copyrights from the University of Alicante in Spain.

She is part of the appeals department of Olivares. She provides legal opinions to clients and is involved in consulting regarding regulatory issues, handling cancellation, nullity and

infringement actions before the Mexican Institute of Industrial Property, as well as handling nullity trials before the Federal Court for Administrative Affairs and *amparo* lawsuits before the federal courts.

ERWIN CRUZ

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Erwin Cruz has been a member of Olivares' life science law group since 2008, helping clients to add value to their businesses and projects in Mexico. He achieves this not only by getting exclusive rights to clients, but also by developing and successfully implementing strategies to enforce exclusive rights and fair trade rules against potential infringers. Erwin provides highly qualified regulatory assistance related to products' marketing, labelling and advertising.

He has extensive expertise in intellectual property rights and regulatory compliance related to the pharma, agro and software industries. He constantly participates in international and national conferences, and meets key authorities in Mexico for these industries, such as the IMPI, the Healthcare Products Regulatory Agency, the Plant Breeders' Rights Office and the Bureau of Consumer Protection.

Erwin has written several articles about litigation and regulations for pharmaceuticals, biotechnologies, agribusinesses, food and beverages.

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