

THE PATENT
LITIGATION
LAW REVIEW

SECOND EDITION

Editor
Trevor Cook

THE LAWREVIEWS

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Editor
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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.

For those of us in Europe, the past year has seen little progress towards the entry into force of the long-heralded Unified Patent Court Agreement, which is the subject of a chapter in this Review. Its ratification by the UK earlier in 2018 leaves the pending challenge before the Federal German Constitutional Court to the consistency of the Agreement with the German Constitution as the only current impediment to its entry into force. But a new impediment now looms with the imminent withdrawal of the UK from the EU as from 29 March 2019, because the Agreement as drafted does not envisage participation by non-EU Member States, an issue that might more readily be addressed were the Agreement to be already in force before such withdrawal occurs. This raises the prospect, unless the German challenge is rejected in the very near future, of having to amend the Agreement before it can enter into force to take account of the UK withdrawal from the EU; either to

reflect its exclusion from the Agreement or, as the UK government has urged, 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

August 2018

MEXICO

Armando Arenas, Luz Elena Elías and Erwin Cruz¹

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 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 pursued 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 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 (PPH) programmes

The IMPI has implemented 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 recently case law issued by the federal courts, it has been ordered to IMPI 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 the 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 must 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. Both the infringement claim and the counterclaim should be decided simultaneously to preclude the possibility of contradictory resolutions.

Separately, the IP law expressly states that a patent cannot be enforced against a third party manufacturing the patented product or using the patented process for scientific or technological investigation, without commercial purpose.

Article 167 *bis* of the Health Law Regulations contains a *Bolar*-type exception, allowing for an application for authorisation of a follow-on drug within three years for chemicals and eight years in advance for biologics of the expiration of the corresponding patent, in order to perform the necessary studies and experiments to obtain the authorisation.

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.

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 no 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, so the strategy is still being tested.

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 request of the Contentious Department, 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).

Standard

Patent invalidity decisions are relatively difficult to obtain. The plaintiff must completely 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 profit 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 deciding 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 mean 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 discretionary 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.

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 Mexican Supreme Court dissects the 40 per cent Rule of Damages

In April 2018, the Mexican Supreme Court published its final written decision, which was preliminarily issued at the end of 2017, relating to the interpretation of the 40 per cent rule for calculating damages. The Court examined whether this rule is appropriate and how it should be applied to the calculation of damages derived from violations of rights protected under the Mexican Industrial Property Law (IPL) covering patents, trademarks and designs (copyrights are governed by a different law and rules).

In summary, the 40 per cent rule establishes that compensation derived from the violation of industrial property rights shall in no case be less than 40 per cent of the sales of the infringing product at the price of sale to the consumers.

The Supreme Court addressed the following questions:

- a whether it was necessary to prove the 'causal nexus' between the illicit act and the damage or harm to plaintiff;

- b* if the 40 per cent rule is to be applied automatically and as a minimum floor to calculate damages;
- c* whether the administrative decision of infringement *per se* – in this case, based on unfair competition – was enough to prove the harm and damage to plaintiff;
- d* if the IP law establishes a compensation for material (economic) and immaterial (moral-reputation) violations;
- e* whether compensation derived from acts of an unfair competition action needs to be proven by actual damages; and
- f* what type of evidentiary items are appropriate to prove damages for compensation under the 40 per cent rule, and whether this rule should be applied only as a method of quantifying compensation or as a type of punitive damages.

ii Ruling

- a* The decision expressly establishes that the validity and constitutionality of the provision establishing the 40 per cent 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.
- b* The administrative declaration of infringement based on unfair competition is evidence of the illicit act, but not of the damages caused to plaintiff.
- c* Unfair competition, defined as an act to induce the consumer to error or deceit, does not necessarily constitute a direct economic harm to the plaintiff.
- d* The plaintiff is required to prove, on a case-by-case basis, evidence of actual harm, material and immaterial.
- e* In the specific case of unfair competition at hand, plaintiff did not offer evidence of actual damages or harm and the infringement decision did not relieve plaintiff from that burden.
- f* The 40 per cent rule is a mechanism to establish the amount of the compensation, but not the damages caused by the illicit act-in this case, unfair competition activity.
- g* The 40 per cent rule is a pre-established method of quantifying the compensation, once all the prongs to claim damages are met.
- h* In general terms, the causes of infringement in the IPL do not contemplate presumption of damages.

iii Conclusions

- a* This was a not a unanimous decision. It was a divided two-to-three decision, of one of the Benches of the Supreme Court. It was not an en banc decision by the two Benches, nor did it constitute jurisprudence; therefore, it is not binding. Notwithstanding, as a precedent, it is highly persuasive and if lower courts issue decisions that differ in the matters of law, such decisions will have to provide strong and lawful arguments to persevere.
- b* The decision does not question the validity of the 40 per cent rule to quantify damages but imposes the burden to prove ‘causal nexus’ on a case-by-case basis.
- c* We tend to believe that civil cases claiming damages derived from clear-cut instances of trademark and patent infringement may be decided differently; however, after the decision under comment, in addition to the evidence to prove the sales of the infringing product, an accurate analysis of the evidence to prove damages should be taken into consideration on a case-by-case basis.

The 40 per cent rule is considered a relief for plaintiffs and a means of compensating for the long term of litigation in Mexico by circumventing the high burden to prove actual damages, lost profits and other damages subject to compensation. This decision does not reject the formula, but accuracy in the evidence of filing civil actions claiming damages derived from the violation of IP rights will be mandatory for plaintiffs.

We also trust that free trade agreements under renegotiation by Mexico with the US and Canada (NAFTA) and the European Union (TELECUEM) will contribute to improving the IP enforcement system in Mexico, which has been a problem for many years, including the rules and venues to claim damages derived from the violation of IP rights.

iv First ruling in Mexico awarding a patent holder damages ahead of the 2018 Supreme Court's ruling

In an innovative strategy to claim damages for its clients, Olivares devised an action that allowed a patent holder of a blockbuster product to collect close to 63 per cent of sales of the 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 the patent infringement actions, the patent holder pursued actions against the generic company's marketing authorisations. These actions ended before district courts, which served the generic company with injunctions to keep such marketing authorisations in force while the court actions were pending a final decision on the merits.

Patent holder achieved a reversal of granted injunctions and reached a final decision before the circuit courts invalidating the generic company's marketing authorisation. Conversely, over the few weeks such injunctions were in force, the generic company gained sales of 26.5 million units.

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

In view of the eventual generic's reluctance to pay, the patentee had to additionally pursue a civil action to execute the awarding ruling. By 2017, after further years of litigation, the patent holder reached not only around 55 per cent of the generic product's sales, but also an additional 17 per cent of the main claimed amount in interest and legal expenses. The patentee expended a lot of effort and time, but prevailed and collected close to 63 per cent of the generic's sales at the end. No other case like this has ever been litigated in Mexico, even after the Supreme Court's recent non-binding ruling.

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 of the case recently decided by the Supreme Court.

IX OUTLOOK

On 27 April 2018, amendments to the IP Law came into force relating to patents, industrial designs and utility models.

The most relevant aspects of this amendment are the following:

- a* The term of protection for designs has been extended to a term of five years, with four possible renewal periods, that is, protection could last up to 25 years, instead of one 15-year term.
- b* Applications for industrial designs must now mention the product to which the design will be applied.
- c* Industrial designs granted before the entrance in force of this amendments, can be renewed for two periods of five years after the expiration of the 15-year period. A renewal petition is due within the last six months of the 15 years protection term originally granted.
- d* Industrial designs under prosecution may enjoy the benefits of the amendments to the law if a petition is filed between 27 April 2018 and 11 June 2018.
- e* Designs, utility models and divisional applications were only published once granted; with the amendments, said applications will be published after a formal examination is complete.
- f* Once a patent, utility model or industrial design application is published, it will be open to public inspection. Under the previous law, such applications could be consulted only by the applicant, the applicant's representative or other authorised persons until granted.
- g* The law reduces the term provided for third parties to submit 'prior art submissions' after publication of an application from six to two months.
- b* Ambiguous terms in the IP Law are defined regarding the requirement for novelty for industrial designs, which before did not define the terms 'independent creation' or 'significantly' as it now states: 'Designs that are of independent creation and that differ significantly from known designs or combinations of known features of designs shall be considered as novel'

Overall, the amendments will be positive for the Mexican IP system, as they provide certainty and fill in several gaps in the IP Law.

During 2018, IMPI has presented draft of amendments to the IP Law related to IP litigation. In this draft, while some amendments pretend to clarify IMPI's powers to impose border measures and to render proof of experts requested by other authorities, other attempts to innovate, such as giving legal worth to notices done by email. Relevant amendments pretend to broaden the type of pieces of evidence that can be submitted in infringement and invalidity actions, to establish standards of Article 34 of TRIPS to declare infringement of patents of processes, to broaden the scope of granted injunctions to imports or exports and digital media, and to set rules for setting amounts of bonds for injunctions and counter-bonds for lifting injunctions. We are following up this draft of amendments, which demands in-depth analysis to secure a positive impact on the IP Mexican system.

ABOUT THE AUTHORS

ARMANDO ARENAS REYES

Olivares

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

Olivares

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

Olivares

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 Patent and Trademark Office, 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.

OLIVARES

Pedro Luis Ogazon 17
Col San Angel 01000
Mexico City
Mexico
Tel: +52 55 5322 3000
Fax: +52 55 5322 3001
armando.arenas@olivares.mx
erwin.cruz@olivares.mx
luz.elias@olivares.mx
www.olivares.com.mx

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