THE PATENT LITIGATION LAW REVIEW

Editor
Trevor Cook

THE LAWREVIEWS

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THE INTELLECTUAL PROPERTY REVIEW

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THE EXECUTIVE REMUNERATION REVIEW

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THE INSOLVENCY REVIEW

THE OIL AND GAS LAW REVIEW

THE FRANCHISE LAW REVIEW

THE PRODUCT REGULATION AND LIABILITY REVIEW

THE SHIPPING LAW REVIEW

THE ACQUISITION AND LEVERAGED FINANCE REVIEW

THE PRIVACY, DATA PROTECTION AND CYBERSECURITY LAW REVIEW

THE PUBLIC–PRIVATE PARTNERSHIP LAW REVIEW

THE TRANSPORT FINANCE LAW REVIEW

THE SECURITIES LITIGATION REVIEW

THE LENDING AND SECURED FINANCE REVIEW

THE INTERNATIONAL TRADE LAW REVIEW

THE SPORTS LAW REVIEW

THE INVESTMENT TREATY ARBITRATION REVIEW

THE GAMBLING LAW REVIEW

THE INTELLECTUAL PROPERTY AND ANTITRUST REVIEW

THE REAL ESTATE M&A AND PRIVATE EQUITY REVIEW

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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 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.

Such disparities 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 main development in patent litigation had been expected to be the entry into force of the Unified Patent Court Agreement, which had been foreseen for early in 2018, even though the UK, a necessary party to the establishment of the new Court, has initiated the procedure under Article 50 TFEU by which it will leave the EU in 2019, and the basis on which it can remain part of the new Court once it leaves the EU is unclear. However, these plans have now been thrown into doubt by the pending challenge before the Federal German Constitutional Court to the consistency of the Agreement with the Federal German Constitution – a challenge that is not expected to be resolved soon. It is to be hoped that by the next edition of this *Review* this particular source of uncertainty will have been resolved and the chapter devoted to this new jurisdiction will by then have practical application.

Trevor Cook
Wilmer Cutler Pickering Hale and Dorr LLP
New York
October 2017

Chapter 15

MEXICO

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

I OVERVIEW

Mexico is one of the leading countries in Latin America, and has recently had 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$2,224,000 million.

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 handle by a specialised bench on industrial 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 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 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 Japanese Patent Office, the Spanish Patent and Trademark 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.

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, 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 to 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 file 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 resolved 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.

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 times the minimum wage (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.

Whether the 40 per cent rule is considered as a punitive damage or whether damages need still to be proved is a question that has remained unanswered, because few cases have reached that stage and there is no case law yet in this regard.

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

A civil action claiming damages must be filed within the next two years after the infringing ruling is beyond the shadow of appeal.

VI OTHER TYPES OF PATENT PROCEEDING

i Linkage regulations

Pursuant to Article 167 *bis* of the Health Law Regulations, at the filing of 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 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, they 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 be 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 New method for assessing patent infringement

Circuit courts in Mexico have unprecedentedly introduced a new method to assess patent infringing activities, in an attempt to mirror the doctrine of equivalence (DOE).

In one case, a patentee demonstrated that a generic drug-maker literally infringed its patent with regard to a pharmaceutical composition. However, as a result of some flow allegations raised by the defendant at the final stage, following dismissal of the case, the circuit courts introduced a new 'peripheral interpretation method'.

The patent in suit covers a pharmaceutical composition that improves the bioavailability of a particular active ingredient. This patent covers the innovator product. The active ingredient is in the public domain.

The invention claimed by the patent in suit mainly consists of a pharmaceutical composition comprising the active ingredient, wherein the composition is adapted to prevent release of the ingredient into the stomach and to release it into the upper part of the intestinal tract. The invention improves bioavailability and stability characteristics of the compositions, and prevents gastrointestinal side effects, among other inconveniences.

Regardless of the fact that the patent in suit has been listed in each edition of the Linkage Gazette since 2006, a generic drug-maker obtained a generic marketing authorisation in 2009. It then started to manufacture and sell a composition with a pharmaceutically acceptable active ingredient salt with enteric coating. Moreover, the generic drug-maker offered to sell its product in a public tender and was unduly awarded.

The patentee implemented multiphase actions related to the marketing authorisation and the public tender award, including a patent infringement action before the IMPI at the first stage, which reached the circuit courts at the last stage.

Further to other allegations, the generic drug-maker essentially argued that the active ingredient is in the public domain, and that enteric coatings are known entities. Separately, they also filed a counterclaim of invalidity. As mentioned below, the patentee actions were successful.

The patentee essentially replied that the case was not about the use of an active ingredient in the public domain or that enteric coatings are known, but about the use of a patented pharmaceutical composition. The patentee also replied, separately, and achieved dismissal of the counterclaim of invalidity.

Regardless of the fact that the generic product is non-exchangeable with the innovator's product, further to other evidence, the patentee demonstrated the infringement through expert proof and a lab test of dissolution profiles of the formulation of the innovator product and the formulation of the generic product.

The test showed that the generic product does not release the active ingredient into the stomach and that it does substantially release it at a specific pH, which is the pH of the upper intestinal tract.

Experts concluded that this implies that the generic product infringed the patent in suit, since it covers a composition that is adapted to prevent release of the ingredient into the stomach and to release it into the upper part of the intestinal tract, and is indicated for the prophylaxis of rejection of transplant in a patient with kidney, liver and cardiac transplant, thus reproducing the matter claimed in the patent.

In other words, the plaintiff proved the patent claims that a pharmaceutical composition is characterised not by its chemical composition, but by its dissolution characteristics and for having an enteric coating. This was reproduced by the generic drug as was duly evidenced according to said test.

Therefore, the IMPI refused the defendant's allegations and ruled it as patent infringer, because the patentee demonstrated a literal infringement of its patent by the generic drug-maker, who had been manufacturing and selling the patented pharmaceutical composition.

This first stage decision was appealed by the generic drug-maker up to last stage before the circuit courts. Further, to restate and paraphrase previous allegations, the generic drug-maker alleged that the enteric coating of its generic product is different from the enteric coating of the drug of reference covered by the asserted patent and, as a result of this difference, that the generic product supposedly did not fall within the scope of the patented claims.

Based on all evidence and arguments provided by patentee, federal magistrates dismissed all generic allegations, upheld the patent infringement ruling because the patentee demonstrated literal infringement, and introduced the peripheral interpretation method to dismiss without doubt those flow allegations by the defendant over the slight difference in enteric coatings of the generic and innovator products.

ii The peripheral interpretation method

The circuit courts found that, in the above case, the generic drug-maker infringed the patent by manufacturing and selling a generic product that contains a patented composition comprising a pharmaceutically acceptable active ingredient salt with an enteric coating. The courts additionally stated that the alleged slight difference in enteric coatings of the generic and innovator products was, in any case, inessential to the claimed invention.

From the content of Article 12, Section V of the Industrial Property Law and Article 29 of its Regulations, the federal magistrates noted the clear intention of the legislator to grant the claim, with a fundamental role in the definition of the purpose of the patent, and to provide more protection to the industrial property, as well as preventing actions threatening such exclusivity or that constitute unlawful competence and, as applicable, eliminating that practice by enforcing the corresponding sanctions.

Based on these reasons, and because, as in other countries of Europe and the Americas, the scope of the patent rights is stated according to the content of their claims, the circuit courts considered that there should be a common system for all nations and, thus, introduced a peripheral interpretation method, which attempts to mirror the DOE. They consider that this method means that the graduation of a possible infringing action is decreed based on identification, within the protective scope of the claims, that shall determine the existence of a possible infringement by identity or by equivalence.

In its ruling summary, the federal magistrates reasoned that a judge must make an analysis using the opinion of an expert in the matter when interpreting the purpose of a patent in an infringement proceeding (regarding the first embodiment). The judge must interpret the vocabulary of an invention and extract its meaning based on the technical context of the claims, and not according to the philological sense of the phrases expressing such claims. In this way, if the expert in the art reaches to the conclusion that the activity claimed includes all the elements of the claims of a previously granted patent, it shall be understood that its attainment constitutes an identical exploitation to that claimed by the latter; therefore, the admissible action is to declare the infringement provided by the law.

Federal magistrates observed that it is a common practice in such proceeding that the activity executed by the alleged infringer includes modifications or variations on the invention, such as adding technical elements, eliminating characteristics of the patented process or changing the technical conditions indicated for its due execution. In that sense, if the expert concludes that, after having analysed the content of the claims, the denounced activity may not be considered identical to the patented activity, then it may make an analysis of the invention regarding the equivalence of the means used.

The circuit courts established that the starting point of this method is the comparison between the purpose of the patent and the purpose of the patent being denounced. The expert must consider:

a elements contained in the claims of the patent;

b evidence of substitution based on his or her own knowledge, and on the elements comprising the state of the art;

c the date on which the possible existence of the infringement is analysed;

d the use of execution embodiments or elements that, despite being a substitute of the invention and possibly interpreted as being in the scope of the claim of the patent, may be excluded because they are considered in the state of the art; and

e innovations and developments after the application date or priority date of the patent allegedly infringed.

If the means used by the alleged infringer are different from those of the patent, and the expert reaches a conclusion from his or her reflection and knowledge (and without developing an inventive activity based on the content of the claims) that with the introduced modifications the same problem of the invention is resolved, then, the assumptions of infringement of a patent shall be met.

IX OUTLOOK

In April 2017, the Mexican Senate added to its legislative agenda consideration of proposed amendments to certain chapters of the Industrial Property Law. Discussion of this proposal is pending, but could result in several positive changes for Mexican IP owners.

Appendix 1

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ARMANDO ARENAS REYES

Olivares

Armando Arenas joined Olivares in 2000 and became a partner in 2017. 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.

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* law suits 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.

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