MEXICO*
(MX)
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A speaker and panelist at numerous seminars in Mexico and the United States, Mr. Olivares, Sr., was also the author of multiple works related to patents, trademarks, transfer of technology and related litigation, and was considered a leading authority on these subjects in Mexico.

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Sergio L. Olivares, Jr. joined OLIVARES in 1987, becoming a Partner in 1994 and Chairman of the Management Committee in 2009. He leads the firm with strength and a commitment to transparency, client satisfaction, and personal service. Mr. Olivares' work at OLIVARES is extensive, and he has vast experience in the prosecution and litigation of intellectual property rights, particularly trademarks, copyrights, patents and unfair competition. He has specialised his practice in all types of intellectual property law, but works closely with the Patent group. Mr. Olivares is highly recommended by leading industry titles and rankings as a leader in IP. He has been influential in ensuring that the firm remains highly innovative as we have added new practice areas and industry groups that offer more complex types of work such as regulatory advice and administrative litigation, in addition to the establishment of the Life Science and IT industry groups. After his graduate work, Mr. Olivares trained with two prominent IP law firms in New York City, Morgan & Finnegan and Kenyon & Kenyon, before joining OLIVARES. This deep understanding of US intellectual property law allows him to offer clients clear comparative analyses of the US and Mexican legal systems and explain complex matters in a way that suits our international clients' needs.

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I. INTRODUCTION

Mexico is a democratic republic with a federal government system. The Mexican legal system has its origin in Roman law and has also been greatly influenced by French law, more particularly by the Napoleonic Code. Thus, it is based on written civil law, although custom has its place within the system. Lawsuits of every type follow a written procedure, with some exceptions to the rule. Generally, jurisprudence and precedents of the Supreme Court and the Federal Circuit Courts are mandatory in decisions of federal judges of the lower courts in litigation and also weigh heavily to the resolutions of administrative authorities.

Article 28 of the Federal Constitution allows the right of the people to legal protection of intellectual and artistic creations or inventive talents, expressly establishing that the Mexican Government may grant temporary "privileges" to authors and artists for the reproduction of their works and to those who invent or perfect something, a temporary "privilege" for the exclusive use of their inventions and improvements. The temporary privilege granted to an inventor for the exclusive use of his invention, that is, the patent, whether by himself or by authorized third parties, originates in the highest law of the country.

The law regulating patents is the Mexican Law of Industrial Property (LIP) published in the Federal Government Gazette of June 27, 1991, amended by publication in the Federal Government Gazette of August 2, 1994, in operation as of October 1, 1994. This law is applied by the Mexican Institute of Industrial Property (IMPI), an administrative agency related to the federal government, created by the federal government by Decree of November 22, 1993, published in the Federal Government Gazette of December 10, 1993.

II. PATENT TOPICS.

There are three recent topics on patent prosecution that should be relevant for patent litigation: the Patent Prosecution Highway pilot program,the pre and post-grant observations procedures and the amendments to the IP Law.

1. Patent Prosecution Highway (PPH).

IMPI launched a PPH pilot program for accepting examinations by United States Patent and Trademark Office (USPTO) and Japan Patent Office (JPO).

The pilot program with USPTO is available since March 1, 2011, and it is likely that will be implemented in a permanent basis. The pilot program with JPO is available for 2 years since July 1, 2011 and with the Spanish Patent Office is pending to be published by IMPI.

In general, PPH is a mechanism enabling applicants to request accelerated examination, based on the search and examination results from an office of first filing, who already determined one or more claims allowable.

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

Olivares & Cia has obtained one of the first patents granted under PPH pilot program.

2. Pre and post-grant observations procedures

On September 20, 2010, came into force a decree reforming several provisions of the LIP related to patent practice, establishing these pre and post-grant observations procedures, which are not a formal patent opposition system.

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

The person filling the information will not be considered as a party and will not have access to the patent file, nor immediate legal standing to challenge a granted patent.

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

It is noteworthy that the original project of reform was promoted by National Association of Drug Manufacturers (ANAFAM), the member companies of which participate mostly in the generic drugs market.

This initial project included, among other issues, two separate pre and post grant opposition proceedings, which would practically delay the granting and therefore the possibility for effective enforcement of patent rights. The project also intended to include additional causes of invalidity related the use of patent rights in activities in violation of the Federal Competition Law.

This project was reviewed (and modified) by the Senate, which determined that the majority of the amendments proposed were unnecessary, including the two issues mentioned above. The final project was ratified by the Chamber of Deputies, without further modification.

Up to the date, the system of "*observations*" has been poorly tested.

3. Amendments to the IP Law

On April of 2017, the Mexican Senate proposed to pass an amendment to some chapters of the Industrial Property Law which is pending of being discussed and approved.

Among the main points included in the proposal related to patents, industrial designs and utility models are the following:

- Incorporates new concepts such as "independent creation" and "significantly" both in relation to requirement of novelty for protecting industrial designs.

- Requires that the design application should indicate the product in which the design will be applied.

- Modifies the term protection of the design, granting a term of 25 years, instead of 15.

- Provides that design and utility model applications will be published after formal examination is complete. Currently, designs and utility models are only published until granted.

- Provides that for all, patents, designs and utility models, divisional applications will be published after the formal examination is complete since nowadays they are not published until granted.

- The proposal includes that once a patent, utility model or industrial design application is published, it will be open for public inspection since currently they can be consulted only by the applicant or his representative, or persons authorized by the same until granted.

- Reduces the term provided to third parties "prior art submissions" after publication of an application from six to two months.

In this regard, we consider that the proposed change in our Law is positive for the Intellectual Property system in Mexico since it will provide certainty and fulfills some gaps in our IP Law.

We expect that discussion of the proposed initiative will take place in the Mexican Congress in September, needless to say that we will you informed about any development related to this reform.

III. PATENT INFRINGEMENT

Article 9 of the LIP establishes that any individual who makes an invention, utility model, or industrial design, or his assignee, will have the exclusive right of exploiting the same to his benefit either by himself or by authorized third parties. This exclusive right is obtained through the corresponding patent in the case of patentable inventions or registration in the case of utility models and industrial designs. Further, Article 25 confers on a patentee the following prerogatives:

(1) If the subject matter of the patent is a product, the right to impede other persons from manufacturing, using, selling, offering for sale, or importing the patented product without his consent, and
(2) If the subject matter of a patent is a process, the right to impede other persons from using said process and from using, selling, offering for sale, or importing the product obtained directly from said process, without his consent.

Working by an authorized licensee, which license has been recorded with IMPI, will be deemed to be effected by the patent holder, unless working is done through a compulsory license.

In Mexico, any patentee or an expressly authorized licensee has the right to prosecute a suit against any third party infringing his rights by virtue of Article 213 of the LIP, which considers the following acts, inter alia, as patent infringement acts:

(1) Manufacturing or producing products covered by a patent, utility model, or industrial design registration without the consent of the holder or without the respective license.
(2) Offering for sale or placing into circulation products covered by a patent, utility model, or industrial design registration, knowing that they were manufactured or produced without the consent of the patent holder or holder of a registration or without the respective license.
(3) Using patented processes without the consent of the patent holder or without the respective license.
(4) 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 license for their working.
(5) Reproducing or imitating industrial designs protected by a registration without the consent of the holder or without the respective license.

In accordance with Articles 187 and 188 of the LIP, either the patentee or the expressly authorized licensee of a registration or IMPI may initiate proceedings for an administrative declaration of infringement of a patent, utility model, or industrial design, complying with the requirements of the law.

1. Claim Construction—Determination of Scope of Claims

Determination of the scope of the legal protection afforded by a patent is imperative in order to estimate the chances of success in patent litigation. In Mexico this is essential because by express provision of Article 21 of the LIP, the scope of a patent is determined precisely by the claims. The claims must be worded pursuant to Article 29 of the Regulations of the LIP in accordance with the following

rules:

(1) The number of claims shall correspond to the nature of the claimed invention.
(2) In the case of there being several claims submitted, they shall be numbered consecutively with Arabic numerals.
(3) They shall not include references to the description or to the drawings, except when absolutely necessary.
(4) They shall be written in terms of the technical characteristics of the invention.
(5) When the application includes drawings, the technical characteristics mentioned in the claims may include reference signs regarding the corresponding parts of those characteristics in the drawings, if that enhances the understanding of the claims. The reference shall be in parentheses.
(6) The first claim shall be independent, and shall refer to the essential characteristic of a product or process whose protection is mainly claimed. When the application includes more than one category of those mentioned in Article 45 of the law, at least an independent claim shall be included for each one of those categories.

    The dependent claims shall include all the characteristics of those claims on which they depend, and they shall describe precisely the additional characteristics that have a congruent relationship with the related dependent or independent claim or claims.

    The dependent claim or claims of two or more claims shall not be the basis for any other claim also dependent from two or more claims at the same time.
(7) Any dependent claim shall include the limitations contained in the claim or claims on which it depends.

It is obvious, then, that there are clear and express rules as to how patent claims must be worded. Accordingly, such rules shall serve as the basis to determine at any particular time the scope and limits of the legal protection afforded to a patentee. Before even considering the possibility of patent litigation, a study should be made as to whether the acts of a third party constitute an infringement of the patent claims.

2. How Courts Understand Patents

Traditionally, the Mexican courts do not address the existence of patent infringement, as in accordance with the LIP such cases must be filed and prosecuted before IMPI. However, the decisions of this agency on patent infringement cases can be appealed by any one of the intervening parties, thus bringing the matter up before the Specialized IP Court of the Federal Court of Administrative Affairs (FCA).

3. Parties Who Can Be Charged With Infringement

Anyone who makes, uses, import, storage, sells or offers to sale a patented product or process, can be charged with infringement, including the Federal Government, according to Article 213 of the LPI.

The doctrine of implied license has never been tested before the Mexican Courts.

4. Foreign Patentees

Considering the constitutional origin of patents and their federal regulation, foreigners and nationals should receive equal treatment before the IMPI and the Mexican courts. Therefore, foreign patentees have the same rights under Mexican law as Mexican citizens do.

5. Parties to Bring Action

The LIP grants the patentee the right to work the invention himself or to confer that right to a third party, that is, to a licensee. In addition, Article 213 of the cited law considers patent infringement to be an administrative violation to the law, but the various sections therein related to patent infringements only indicate which acts constitute an infringement. The law does not expressly establish who can take action against an offender. However, there is no doubt that both the patentee and his successors and assignees are entitled to take action. The State can also take action in cases where it has acquired a patent through expropriation for reasons of public interest. On the other hand, Article 68 provides that, unless provided otherwise, a licensee can take legal actions against infringers of the licensed patent, provided that the license is recorded before IMPI.

The decree reforming several provisions of the LIP that came into force on September 20, 2010, above mentioned, adding a provision defining the act of attempting an infringement action when a previous request for infringement has been denied, referring to the same patent.

Likewise, an accused infringer may counterclaim patent invalidity under formal or technical considerations, upon receiving the infringement suit before the IMPI, but it is not possible to request an additional judicial ruling or declaration.

Cease and desist letters provide the required legal standing to initiate invalidity actions. If pertaining to a specific industrial or commercial activity (i.e. the pharma industry), to provide legal standing, this is subject to debate and the Courts are divided.

Amendments to the patent law allow anyone to request the IMPI to initiate officiously the cancellation proceeding against patents.

It is worth mentioning that simple legal standing, namely the mere business or commercial activity to challenge the validity of patent is under test before the courts.

6. Choice of Jurisdiction and Venue

Usually, in Mexico, the problem of selecting the competent judge or choosing jurisdiction was minimal. Indeed, the only venue to enforce a patent is through administrative proceedings (infringement action) before the IMPI, which is located and operates in Mexico City and now at five of the main Mexican cities, Zapopan, Monterrey, Merida, Leon and Cholula. However patent administrative infringements actions are heard only in Mexico City, as the offices at other cities only receive complaints but cases are remanded to Mexico City.

However, when it comes to the assertion of civil actions, the plaintiff may choose a federal or a state court provided that the patent infringement does not affect government interests. The plaintiff will have to follow the rules established in the Code of Civil Procedures to determine the judge with proper jurisdiction.

Once IMPI's resolution was beyond a shadow of appeal, a civil suit could be primarily based on article 221 bis of the LIP filed before the civil courts, claiming damages against the infringer, where it is set forth that the indemnification for damages caused by an industrial property rights violation shall not be in any case less than 40% of the sale price to the public of each infringing product or service rendered that involves a violation to the rights of the affected titleholder.

Certainly, when bringing a damage action before a Civil Judge against the same alleged infringer, arguing that the unauthorized use of a patented process is an unlawful act, in both instances, IMPI and the Civil Judge would need to determine whether an infringement is being committed. However, there is the risk of obtaining contradictory resolutions, as IMPI could resolve in favor by considering that there was a patent infringement whereas the Civil Judge could resolve to the contrary.

However, the Mexican Supreme Court decided the controversy. It considered that according to the Mexican Industrial Property Law system, an administrative agency IMPI is the only authority to decide and sanction IP rights infringements. Thus, the Supreme Court decided that in order to claim damages

derived from a violation of an IP right, such infringement should be declared by IMPI beyond shadow of appeal.

Based on such jurisprudence, currently it is unsuitable to first or simultaneously file a claim of damages together with a patent infringement procedure, unless there would be a full change in the law and the Mexican enforcement system.

7. Education and Training of Judges

The IMPI, which is the authority empowered to issue an administrative resolution on patent infringement cases, has a staff that possesses both the formal education and the technical qualifications needed to perform the task entrusted to it.

Before 2003, in patent litigation an appeal against the decision of the IMPI used to be filed and prosecuted before any of the sixteen Administrative District Courts located in Mexico City. A central filing room of these courts turns the appeals to any one of the existing sixteen courts. In this stage of patent litigation, whether or not the judge had technical knowledge is a somewhat secondary considerations since, as explained in more detail later, the appeals deal with the legal rather than the technical aspects of the case. This caused many delays in trials, as appeal proceedings would merely result in instructions to the issuing authority, which could lead to new appeals.

Starting in 2003, the Federal Court of Administrative Affairs (FCA) in Mexico was granted extended jurisdiction to include the review of challenges against the acts of most federal administrative authorities, including the IMPI and the Mexican Copyright Office (INDAUTOR. In 2006, a specific law was issued to regulate the proceedings before the Federal Court of Administrative Affairs (FCA), the Federal Contentious Administrative Proceedings Law (FCAPL). According to this Law, the FCA has full jurisdiction to review the acts of administrative authorities, including in some cases studying *de novo* the original files, and deciding on their merits.

In 2008 the FCA determined to create a Specialized Court for Intellectual Property Matters, in order to improve the quality of the decisions in this area of Law. This Specialized IP Court began working since January 2009.

There are a considerable number of associates and academic Institutions related and unrelated with the "Judiciary" (Judges and Magistrates) at all level, which regularly organize seminars and lectures to promote, study and discuss IP issues directed to and/or along with Judges and Magistrates.

8. Proving Infringement

The Mexican Industrial Property Law (LIP) grants a patentee the right for the exclusive exploitation of the patented invention. Therefore, a patent gives the right to exclude others from making, using, offering to sale or importing the covered invention. Briefly, in a patent infringement action the plaintiff must prove the following:

(1) Ownership or recorded license over a granted, valid and full in force patent. Generally, certified copy of the file wrapper of the patent prosecution is enough to prove these requirements. However, validity of the patent may be challenged by defendant.
(2) Someone uses, makes, offers to sell, or imports the patented invention. The Mexican LIP establishes direct infringement over the manufacturer. However, infringement against sellers requires evidence of prior notice of the alleged infringement. When plaintiff claims infringement of a patented process, defendant has the burden of proving the usage of a different process other than the one patented. There are no grounds on the LIP to apply contributory in-

fringement doctrine, namely the action against the persons who assist direct patent infringers only.

(3) The usage of invention covered by the patent. Pursuant to the Mexican LIP, literal infringement is recognized only, no infringement under the doctrine of equivalence is provided. Plaintiff should prove that the wording of the patent's claim or claims cover the alleged infringing product or process. First, plaintiff must define the scope of the approved claims. The LIP provides that the span of the claims is determined by the wording of the claims aided by the description and drawings. Interpretation of the claims and the use of the patented invention on the infringing product or process are technical issues. Therefore, infringement actions may require proof of experts even though the Technical Area of the Mexican PTO will render an internal technical report to its legal area as an expert in patent matters. However, please be advised that such internal report is not supported in the applicable procedural law and it could be objected to by some of the parties. In addition, there are certain new legal tools such as the Linkage Gazette in order to prove patent infringement of pharmaceutical products.

About evidence under the general principles of Mexican law, the person who affirms is obligated to prove. Thus, a plaintiff in patent litigation is required by the law to prove the existence of the infringement. In this respect, the LIP does not regulate the manner in which an infringement is to be proven. Consequently, the Federal Code of Civil Procedures is applied as a supplement to the LIP.

Under the Federal Code of Civil Procedures, the following are accepted as evidence: (1) depositions; (2) public documents; (3) private documents; (4) expert testimony; (5) judicial audit or inspection; (6) witnesses; (7) photographs, writs, and stenographic notes, and in general all other elements stemming from scientific discoveries; and (8) presumptions.

The IMPI, however, has rejected confessional and testimonial evidence unless they are rendered through an affidavit.

(4) Without authorization. The burden of proving authorization is on defendant. The doctrine of implied license has never been tested before the Mexican courts.

On January 27, 2012, the Industrial Property Law was amended, with the most relevant issues relating to enforcement of IP rights entering in force on January 30, 2012. Under the amendments, opposing an inspection visit (impeding the entrance of a IMPI's inspector to an alleged infringer's premises) will cause two sanctions:

- The facts intended to be proven with the visit of inspection will be presumed correct, and;
- Any opposition to a visit will be considered an infringement itself.

Lack of compliance with an order for documents or information to be produced is also now considered an infringement.

Before these amendments entered into force, the Law did not expressly provide any sanction for opposing an inspection visit, or failing to produce documents or information. These amendments will discourage infringers from not complying with IMPI orders, giving IMPI greater strength on these matters.

Although it is not clear if the new infringement causes will be studied and resolved in the same proceeding in which such causes are originated, or if it will be necessary to initiate new proceedings, they are new tools that will certainly help IP owners in the enforcement of their rights.

Likewise, we consider that with these amendments, an infringer's activities will be to some degree controlled, at least during proceedings.

IV. ADMINISTRATIVE STAGE OF PATENT INFRINGEMENT SUIT AND REMEDIES

1. Decision of IMPI

Proving patent infringement in Mexico is a difficult task in a country which follows a strict Civil Law system full of formalistic rules for both evidence and proceedings. IMPI may declare or deny the patent infringement, or cancel the patent, if a counterclaim was filed.

A defendant of a patent infringement action can file an invalidity action against a patent as a counterclaim, when filing the response to the infringement action. An independent invalidity action can be filed, but if it is not filed along with the brief of response to the infringement action, such action would be separately decided from the infringement, when the invalidity action is filed as a counterclaim IMPI is legally bound. Both the infringement claim and the counterclaim should be resolved simultaneously to preclude the possibility of contradictory decisions. IMPI shall dismiss the patent infringement if the patent is declared null in the counterclaim.

It is worth mentioning that IMPI does not make available to the public the judgments of patent infringement trials or any proceeding until they are final and beyond shadow of appeal and some information of the decision remains confidential especially if the parties request it.

2. Federal Law of Administrative Proceedings and Its Effects on Industrial Property Matters.

For many years the only way to contest a decision from IMPI, including those related to litigation proceedings, such as cancellation and infringement actions, was by taking an Amparo suit before a District Court. However, this traditional route has been altered by the application to IMPI decisions of the Federal Law of Administrative Proceedings (FLAP). The FLAP is intended to be a supplemental statute to administrative laws, the Law of Industrial Property (LIP) included, and the interpretation of such supplementary nature by the authorities involved, namely IMPI, the District Courts and FCA (former Federal Tax Court).

The FLAP began its operation on June 1, 1995, one of its main purposes being the standardization of administrative procedures by virtue of its supplementary application to almost all existing statutes of administrative nature. However, at that time this law did not cover acts of IMPI or of any other decentralized agency.

In view of certain amendments to the FLAP, in operation since May 19 and 31, 2000, its supplementary application was extended to acts of IMPI and from other decentralized bodies. On the other hand, the FLAP establishes that decisions from administrative authorities, such as IMPI, can be contested either with a so-called Review Recourse filed before the authority issuing the decision or with a claim filed before the FCA.

The FLAP establishes a fifteen working-day term to file the Review Recourse as of the date of the notice of the contested resolution and this recourse is decided by the administrative superior of the person who issued the resolution at IMPI. The Review recourse is advisable when the resolution is founded on a clear mistake of IMPI (i.e., a denial based on an alleged lack of a particular document).

On the other hand, there is a term of thirty working-days to file the corresponding appeal before the FCA.

Therefore, IMPI's decisions may be commonly appealed before IMPI itself through the Review Recourse or by an appeal filed before the FCA. The decision issued by the FCA could be appealed before 20 Federal Circuit Courts at Mexico City, however the case is turned randomly by a computer system. By territorial jurisdiction, IP matters are mainly decided at Mexico City.

V. PRETRIAL REMEDIES

Amendments to the LIP, effective October 1, 1994, provided for the first time in the history of intellectual property litigation so-called provisional injunctions whereby the IMPI can take certain important measures against defendants which are listed in Article 199 bis.

If the plaintiff chooses to ask the IMPI for a provisional injunction, a bond will be fixed to warrant possible damages to the defendant. This injunction is to be petitioned in writing, and within a term of 20 days from its execution the plaintiff is required to file a formal written claim of infringement. Failure to do so will cause the plaintiff to lose the bond in favor of the defendant. This party has the right to place a counter-bond to stop the effects of the provisional injunction, which amount will have to be 40% higher than the amount of the bond posted by the plaintiff. The defendant has the right to allege whatever he may deem pertinent with respect to the provisional injunctions within a term of 10 days from the date of execution.

The provisional injunctions established in various sections on Article 199 bis are:

(1) Order the recall or impede circulation of the merchandise that infringes upon the rights protected by the LIP.
(2) Order that the following be withdrawn from circulation:
    (a) The articles illegally manufactured or used;
    (b) The articles, packaging, wrappings, stationery, advertising material, and other, similar items that infringe upon any of the rights protected by the LIP;
    (c) The advertisements, signs, posters, stationery, and other, similar articles that infringe upon any of the rights protected by the LIP; and
    (d) The utensils or instruments destined for or used in the manufacture, production, or obtainment of any of the concepts indicted in paragraphs (a), (b), and (c).
(3) Immediately prohibit the marketing or use of the products with which any rights protected by the LIP are violated.
(4) Order the attachment of the products, which will be conducted as provided in Articles 211 to 212 bis 2 of the LIP.
(5) Order the alleged transgressor or third parties to suspend or cease all acts that constitute a violation of the provisions of this law.
(6) Order a suspension of service or the closing of the establishment when the measures indicated in the preceding paragraphs are insufficient to prevent or avoid the violation of rights protected by the LIP.

If the product or service is in trade, the merchants or service providers will be required to refrain from selling the product or rendering the service as of the date of notification of the resolution.

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

The IMPI, to grant the so-called provisional injunctions, requires the petitioner to comply with the following:

(1) Provide evidence showing that he is the holder of the right and proving any one of the following hypotheses:
    (a) The existence of a violation of his right;
    (b) That the violation of his right is imminent;
    (c) The existence of the possibility of suffering an irreparable damage; and
    (d) The existence of a grounded fear that the evidence may be destroyed, concealed, lost, or altered.
(2) 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 in this prong

would be that the law and the regulation are silent about the rules and parameters for IMPI to fix the amount of the bonds and eventual counter bonds to lift the preliminary injunctions.) (The full discretion of IMPI in this regard has caused certain inequities that also provoked the continuation of the infringing activity rather than discourage the infringer due to the contingency.)

(3) 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.

The LIP also establishes in Articles 199 bis 3 and 199 bis 5 important provisions as follows:

Article 199 bis 3. The petitioner of the provisional measures referred to in Article 199 bis will be liable for payment of harm and damages caused to the person against whom the measures was taken, when:

(1) The definitive and firm resolution regarding the substance of the controversy decrees that there was no violation or threat of a violation to the rights of the petitioner of the measure, and

(2) A provisional measure has been requested and the claim or petition for an administrative declaration of infringement is not presented to the competent authorities or to the IMPI regarding the substance of the controversy within 20 days from the date the measure was executed.

The defendant has the right to place a counter bond to have the effects of the provisional injunction stopped, which amount will have to be 40% higher than the amount of the bond posted by the plaintiff.

Likewise, the defendant has the right to allege whatever he may deem pertinent with respect to the provisional injunctions within a term of 10 days from the day of the execution.

According to the Article 199 bis 5. the IMPI will decide in the final resolution of the procedure for an administrative declaration of infringement whether the preliminary injunctions that were adopted will remain firm or will be discharged, if they were not lifted before by a counter bond.

VI. PRETRIAL SETTLEMENT

There are no legal limitations with respect to a prior out-of-court settlement, and the parties can stipulate any clauses they wish, provided that the terms of the settlement are not contrary to legal provisions, custom, or proper commercial or moral usage. A settlement does not require any government approval or registration with the IMPI. However, if the settlement is reached while provisional injunctions are in effect or a patent infringement action has been filed at the IMPI or has reached the courts, the corresponding settlement agreement has to form part of the official records at the IMPI or in the courts.

1. Statute of Limitations for Patent Infringement Claim

The LIP is silent on the matter of a statute of limitations. Thus, the patentee may bring a patent infringement action before IMPI at any time while the patent is in force. No laches defense is recognized by the LIP.

VII. PATENT INFRINGEMENT SANCTIONS AND DAMAGES

Article 214 of the LIP establishes sanctions for acts that are considered as administrative infringements, patent infringements included, provides that such acts will be sanctioned as follows:

(1) A fine of up to 20,000 days of the minimum general wage prevailing in the federal district;
(2) An additional fine of up to 500 times the minimum general wage prevailing in the federal district for each day during which the infringement subsists;
(3) Temporary shutdown for a period of up to 90 days;
(4) Final shutdown;
(5) Administrative arrest for up to 36 hours.

In the event of a recurrence, the previously imposed fines will be doubled, but the amount thereof shall not be more than three times the maximum set forth in Article 214 of the LIP, depending on the case. IMPI usually only imposes fines as sanctions.

The sanctions established in the LIP will be applied in addition to the indemnification for harm and damages inflicted upon the affected party, in the terms of civil law and without detriment to the provisions of Article 221 bis, which provides: The repair of material damages or the indemnification of harm and damages resulting from a violation of the rights conferred by this law will never be lower than 40 percent of the sale price to the public of each product or the rendering of services that implies a violation of any one or more of the industrial property rights regulated by this law.

If the infringing party continues committing the infringement activities notwithstanding that a decision of the IMPI on the merits of the infringement claim became firm (i.e., beyond the shadow of an appeal), the re-offense is considered a crime and penal actions can be taken against the infringer. Such actions are taken by the Federal Prosecutor's office, which conducts a so-called preliminary investigation. If this criminal authority concludes that there is recidivism, then it turns the matter over to a criminal judge for trial. It is important to note that the Federal Prosecutor, before turning the matter over to a criminal judge for trial, must request the IMPI to issue a technical opinion on the merits of the administrative infringement case, which will not prejudge any criminal action.

For a patent infringement that is considered a crime, the penal sanction is from two to six years' imprisonment and a fine of 100 to 10,000 days of the minimum general wage prevailing in the federal district.

Independently of any criminal action taken, the party adversely affected by any of the criminal offenses to which the LIP refers may demand from the one or more infringers the repair of the caused harm and the payment of damages suffered by patentee as a result of said criminal offense.

Mexican law recognizes the existence of damages stemming from contract default and damages stemming from illicit acts or acts against good customs that injure a third party. In other words, there are damages caused by criminal offenses and civil damages (contractual or noncontractual) caused by illicit acts that are not considered criminal offenses.

Under Mexican doctrine and positive law, harm is understood as the loss or diminishment suffered by a person's equity from default on an obligation or as the result of an illicit act. Understood as damage is the impairment of legal gain that should have been obtained through the fulfillment of an obligation or if an illicit act had not been committed.

It is very important to consider that under Mexican doctrine harm and damage must be the immediate and direct result of a default of an obligation or of the commission of an illicit act.

VIII. TRIAL PROCEEDINGS

1. How to Bring Action

The procedure related to a patent infringement in the IMPI was relatively simple; however, patent infringement actions are currently more sophisticated and preparation of a claim by a plaintiff may be complex. It is highly important to bear in mind that the plaintiff should file his claim together with all documents on which the action is based and which will be used as evidence.

When the IMPI admits a claim, it serves notice to the defendant, who must answer it within the short term of 10 days. The defendant, on filing his answer, must also present all documents on which

his defense will be based.

Government Fees to commence a proceeding (patent infringement or invalidity) before IMPI are around US 73. The proceeding before IMPI usually lasts two years.

In a complaint against an infringer of patent rights, particular care should be given to two aspects: one is of form, that is, the power of attorney, and the other is of substance, that is, the arguments and evidence on the technical aspects that constitute patent infringement.

2. Power of Attorney

The power of attorney granted by the patentee to his attorney for the latter to file and handle a patent lawsuit should be carefully considered in order to preclude the possibility of a very customary defense in Mexico, an attack on the validity of this document.

The problem arises when the power of attorney is granted on behalf of a corporation, since a power of attorney granted by an individual need only be executed in the presence of two witnesses, legalization by the Mexican Consul, or by the Apostille being dispensed with the express provision of the law (Article 181 of the LIP). In contrast, in the case of powers of attorney granted on behalf of corporations, the LIP has set certain standards allowing this document to be granted in accordance with the applicable law of the land where it is granted or in accordance with international treaties. Nevertheless, it still requires proof of legal and present existence of the corporation; proof of the domicile of the corporation; proof that the power of attorney is granted to carry out acts within the scope of the corporation; proof that the officer of the corporation signing the document was duly empowered to do so; and proof that said officer was in turn empowered by a legally appointed board of directors or by the stockholders meeting or by virtue of the law. These requirements may form part of the power of attorney itself or of a separate notarial certificate attesting to said corporate points, which should be notarized and thereafter legalized by the Mexican Consul or authenticated with the Apostille, together with the power of attorney itself.

For certain countries of the Americas, the Protocol on the Uniformity of the Legal Regime of Powers of Attorney aims to standardize and reduce requirements. Certain countries of the Americas adhere to this protocol, and the power of attorney forms used by Mexican specialist attorneys conform to the protocol. Careful processing of such forms is essential.

3. Technical Arguments

Of equal, if not greater, importance is how to address the patent infringement from a strictly technical point of view in the complaint filed with the IMPI.

Prior to litigation, the patent counsel should make a comparative study between the allegedly infringing elements and the scope of the patent's claims. This study and the conclusions supporting the infringement should form a part of the complaint brief, that is, in the part where the facts are narrated.

The IMPI can base its decision only on what the plaintiff and the defendant allege; there would be a violation of individual rights if the IMPI were to decide the case on the basis of facts not included in the briefs by either the plaintiff or the defendant.

Infringement actions require proof from experts even though the corresponding Technical Center of IMPI may render a technical report as an expert in patent matters. Expert evidence should be offered in the complaint, indicating the points on which the expert will deliver his opinion.

Proving patent infringement in Mexico is a difficult task in a country that follows a strict civil law system of formalistic rules for both evidence and proceedings.

It is worth mentioning that recently a Circuit Court ruled on behalf of a pharmaceutical company considering that the peripheral interpretation method on which the claims are structured as the essential element and basic reference of the patent system is now the applicable standard to Mexico.

The Circuit Court considered the above due to two reasons: the first one, because according to the Mexican rules and regulations, the intention of the legislator to grant the claim with a fundamental role

in the definition of the subject matter of the patent is very clear and, the second one, since this rule allows that the State protects in more extent the industrial property and to prevent actions affecting such exclusivity or that constitute unlawful competence and, if applicable, eradicate this practice by means of the imposition of the corresponding sanctions.

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

Such method of interpretation represents the contribution by the US court precedents to render flexible the rigidity of the words used in the drafting of the claims and the scope and affectation of their content to the reality of the specific case.

IX. POST-TRIAL CONSIDERATIONS

1. Enforcement of Decision

It is important to keep in mind that patent infringement is considered under the LIP as an administrative violation of the law. The proceedings in the IMPI will conclude with a decision that, if favorable, will impose administrative sanctions on the defendant ranging from fines of up to approximately US $60,000 to temporary or definite closure of the infringing business and even administrative arrest for 36 hours. The IMPI usually imposes fines. However, if the defendant continues committing the infringement, the fines will be double the amount mentioned before, and if the illicit conduct continues notwithstanding that a decision of the IMPI on the merits of the administrative infringement claim became firm (i.e., beyond shadow of appeal), it is then considered a crime, so penal actions can be taken against the defendant.

2. Settlement of Case

A patent litigation can be concluded by a settlement between the parties that can take place at any time during the proceedings at the IMPI or even during the proceedings in the Federal Courts. The terms of the settlement are limited only by the will of the parties, and payment of damages can be included. A settlement agreement can be enforced in the courts to obtain performance or to resolve any controversy arising out of its interpretation. It is also possible to use arbitration as a mechanism for resolving a controversy over a patent infringement if the parties involved agree to do so.

3. Effect of Decision on Other Countries and on Third Parties

The final decision of the IMPI in a patent infringement case can only have effects in the Mexican Republic.

4. Recovering Damages Under Bonds in Industrial Property Infringement Cases in Mexico

The LIP establishes that a petitioner of preliminary injunctions will be responsible for payment of possible damages caused to the party against which said injunctions will be implemented, thus the petitioner is requested to post a bond. Defendant is allowed, however, to post a counter bond to release the preliminary injunctions.

In compliance with Article 199 Bis 4 of LIP, the Mexican Institute of Industrial Property will place the bond or counter bond at the disposal of the party that won the litigation when the decision of IMPI becomes final, that is, beyond shadow of appeal.

Article 221 Bis establishes that the award to plaintiff in infringement cases cannot be less than 40% of the sale price to the public of each infringing product or service. This legal provision literally

applies to plaintiff only. However, defendant who obtained a favorable decision can sustain that this legal provision may apply also to defendants by analogy. This last possibility has not been tested at courts yet.

To recover damages posted under a bond, the first following legal proceedings are available: (a) Petition before Bonding Company; (b) Claim before National Commission for the Protection and Defense of Financial Services Users (through a settlement agreement or arbitration); and (c) claim before Civil Courts. In any event, to recover damages under bonds, petitioner plaintiff must show and prove actual damages. In general, the decisions issued in patent litigation cases do not state the amount of damages accrued on behalf of the wining party. Thus, it is advisable to prove and determine this amount through the Civil Courts.

X. DEFENDING A PATENT INFRINGEMENT SUIT

1. No Infringement

This defense is based on the argument that the alleged infringing conduct does not constitute infringement because the due interpretation of the claims does not read on the allegedly infringing product or process.

2. Challenging the Validity of Patents

Under the LIP, patents are valid until the contrary is proven. Article 78 of the LIP establishes a series of grounds upon which a patent can be invalidated.

One of the most common defenses in patent litigation in Mexico is to attack the validity of the patent allegedly infringed. However, since the patent exists, an administrative resolution is required to declare its annulment. This defense 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 who filed the original complaint. Both the infringement claim and the counterclaim should be resolved simultaneously to preclude the possibility of contradictory resolutions. The grounds for invalidating a patent as established in Article 78 of the LIP are the following:

(1) When it was granted in contravention of the provisions on requirements and conditions for the grant of patents or registrations of utility models and industrial designs. Considered as requirements and conditions for the grant of patents and registrations are those established in Article 16, 19, 27, 31 and 47 of the LIP.
(2) When it was granted in contravention of the provisions of the law in effect at the time when the patent or registration was granted.

The nullity action based on this section may not be based on a challenge of the legal representation of the applicant when prosecuting and obtaining a patent or a registration.
(3) When the application is abandoned during its prosecution.
(4) When the grant is defective because of error or serious oversight, or when it is granted to someone not entitled to obtain it.

The nullity action mentioned under (1) and (2) may be taken at any time; the action under (3) and (4) may be taken within five years, counted from the date on which the publication of the patent or registration in the Gazette becomes effective.

When the nullity affects only one or some claims, or a part of a claim, the nullity will be declared only with respect to the affected claim or the part of the claims affected. The nullity may be declared by way of a limitation or precision of the respective claim and the cancellation of the claims has retroactive effects as to the filing date, according to Article 79 of the LIP.

Article 16 provides that inventions are patentable when they are novel, are the result of an in-

ventive activity, and have an industrial application, excepting:

(1) Processes which are essentially biological for the production, reproduction, and propagation of plants and animals;
(2) Biological and genetic material as found in nature;
(3) Animal breeds;
(4) The human body and the living parts that compose it; and
(5) Plant varieties.

Article 19 establishes the subject matter that cannot be considered as an invention, these being the following:

(1) Theoretical or scientific principles;
(2) Discoveries consisting of making known or disclosing something that already existed in nature, even if previously unknown to man;
(3) The schemes, plans, rules, and methods for carrying out mental acts, games, or businesses and the mathematical methods;
(4) Computer software;
(5) Forms of presentation of information;
(6) Aesthetic creations and artistic or literary works;
(7) The methods of surgical or therapeutic treatment or diagnosis applicable to the human body and those relating to animals; and
(8) The juxtaposition of known inventions or mixtures of known products and their variation of use, form, dimensions, or materials, unless they actually are combined or merged in such manner as not to be able to operate separately or that the qualities or characteristic functions thereof are modified to obtain an industrial result or use not openly apparent to a person versed in the subject matter.

Article 27 provides that utility models will be registerable provided that they are novel and have an industrial application.

Article 31 establishes that industrial designs will be registerable provided that they are novel (originality standards) and have an industrial application.

Article 47 relates to the specification and claims in a patent application requiring:

(1) A description of the invention, which shall be sufficiently clear and complete to allow it to be fully understood and, in such case, to guide its implementation by someone having medium skills and knowledge in that field. It shall also include the best method known by the applicant to put the invention into practice, when it is not clear from the description of the invention.

    In the case of biological material in which the description of the invention cannot be set forth in detail in itself, the application must be supplemented by a proof of deposit of said material at an institution recognized by the IMPI, pursuant to the provisions of the regulations of this law.
(2) The claims can be one or more, which shall be clear and concise and may not be broader than the contents of the description.
(3) An abstract of the invention, which will be used solely for the publication and as an element of technical information.

3. Rights of Prior Use and Other Limitations to Rights Conferred by a Patent

An effective defense can be based on the fact that the defendant was already using the same in-

vention covered by the allegedly infringed patent, or a substantially similar invention, prior to the filing date of the corresponding patent application in Mexico. In this respect, Article 22 of the LIP establishes that the rights conferred by a patent will have no effect with respect to anyone who, prior to the date of filing the application in Mexico or the validly claimed priority, manufactures the product or uses the process covered by the patent or takes the necessary steps to carry out such manufacture or use. It is clear then that this hypothesis also offers defense possibilities in a patent infringement suit.

From the technical standpoint, the appropriate defense would be to destroy with technical elements a claim by the plaintiff that the defendant's product or process constitutes a patent infringement by virtue of its similarity to what the plaintiff has a right to under the claims of his patent.

A limitation of patent rights is provided in Article 22 of the LIP, establishing that a patent will not have any legal effects (Section II) against anyone who trades with, acquires, or uses the patented product, or the product obtained by the patented process, after such product has been legally introduced into trade. It has been interpreted by Mexican scholars that this limitation to patent rights does not mean that importation into Mexico of so-called "gray goods," consisting of products patented in Mexico or obtained through a patented process in Mexico, is permitted under Mexican law. The importation of this type of product, to be considered licit, must have been done by the patentee or his licensee.

XI. PATENT LITIGATION AND ISSUES RELATED TO PHARMACEUTICAL PATENTS

1. Public Tenders

Several pharmaceutical companies in Mexico had faced an unpleasant situation in public tender proceedings, due to a lack of respect by Health Authorities of patent rights.

The Mexican Institute of Social Security (IMSS) and the Institute of Social Security and Services for Government Workers (ISSSTE) are the main purchasers of pharmaceutical products in Mexico. These two Mexican health authorities have faced an extremely bad financial situation during the previous ten years, up to the point that they have mentioned to the media that they are very close to bankruptcy, which is an alarming situation especially because these two entities are in charge of providing social security, health services and medicines to private and government workers in Mexico.

We strongly believe that this pessimistic scenario on the financial situation of ISSSTE and IMSS has caused that these entities seek the acquisition of medicines at the lowest price available, and they are finding cheap pharmaceutical products in generics and even in pharmaceutical products that infringe patent rights.

The law that regulates public tenders before IMSS and ISSSTE is the Federal Acquisitions Law, which in its Article 41 Section I, established that regarding the acquisition of patented products, the public contract (agreement for acquisition) should be directly awarded to the holder of the rights derived from the patent.

Notwithstanding the above, in order to acquire said cheap pharmaceutical products, the Health Authorities have been implemented certain unlawful strategies, which have been affecting the patent rights of pharmaceutical companies. The legal actions that these companies have taken to prevent said strategies have caused the Health Authorities to come up with new excuses in order to bypass patent rights, as is briefly exposed in the following historical summary:

a) When this issue began taking place, and the holder of the rights derived from a patent attempted to enforce Article 41 Section I of the Federal Acquisitions Law in a public tender, ISSSTE and IMSS in a very insufficient manner justified their awards on behalf of third parties, different from the owner of patent rights, under the consideration that they did not have jurisdiction nor the capacity to study and decide over industrial property matters, specifically regarding the scope of rights derived from a granted patent.
b) Thereafter, the health authorities misinterpreted the wording of Article 41 section I of the Federal Acquisitions Law, considering that it provides an unrestricted discretion to decide on

public tender processes at will, based on the results of the tender award supply contracts. In these cases Olivares & Cia fashioned in arguing that the word "*may*" in Article 41 (as in "*the authorities may hire acquisitions and services without a public tender procedure*") did not afford the authority an unrestricted power to overlook patent rights. Our firm had challenged this unfortunate interpretation by mentioning, inter alia, that Article 28 of the Federal Constitution grants a patentee the privilege of exclusive working of patented inventions. In addition, the LIP clearly confirms said exclusive right. The term "may" in the Federal Acquisitions Law generated a conflict with both our Constitution and our patent law, undermining the exclusive privilege of working a patent. This reasoning gave basis for an argument directed to the unconstitutional interpretation conducted by IMSS and ISSSTE of Article 41 Section I of the Public Acquisitions Law.

c) When Olivares & Cia firm challenged said Authorities' misinterpretations of the law, they came up with a new justification to their acts, based on certain provisions of international treaties, such as NAFTA and the Free Trade Agreement with the European Community. In short, the Authorities disqualified patented pharmaceutical products coming from abroad due to a wrongful interpretation of said international treaties, which establish a grace period for certain products to be benefited from said free trade treaties. However, said limitations only apply to non-patented products and not for products covered by patents in force. Therefore, the exclusive rights derived from the patents should not be disregarded by a vague interpretation of the international treaties as wrongly decided by ISSSTE and IMSS.

d) Once the Linkage System was in force as of September 20, 2003, and the first edition of the Linkage Gazette was published back on November 17, 2003, including more than seventy patents that cover active ingredients only, IMSS and ISSSTE disregarded in public tenders any patent that was not published in said Gazette. The main problem with this Gazette was that the publication was incomplete, since the IMPI did not include any patent that was under litigation, or that had been subject to a correction or extension in its life term. Due to this, we had to request IMPI to issue official communications regarding specific patents, to be filed at public tender proceedings, stating among other issues, that certain patents not published in the first edition of the Extraordinary Gazette also cover active ingredients and they were subject to be published in the second or next edition.

e) Other excuse by IMSS and ISSSTE was that the titleholder or the licensee of the patent is not the same person that usually participates in public tenders; under this ridiculous argument the authorities were again disregarding patent rights. Olivares suggested to his clients that in the tender processes, they should file the patent letter, the recordation of the corresponding license and the distribution agreement with the company that usually participates in public tenders.

From everything mentioned above, it is easily discernable that there are several obstacles to overcome when enforcing patent rights of pharmaceutical products, thus we have shaped certain lines of legal and practical actions to pursue said enforcement, such as the following:

(1) Take up strong lobbying efforts before IMPI and if necessary, take the legal actions available to obtain the publication of all patents granted to allopathic medicines in the Linkage Gazette.
(2) As we mentioned below, contest the lack of publication in the Linkage Gazette. In this regard we suggest the filing of a constitutional action, so called Amparo suit, contesting the lack of publication of patents.
(3) Contest the awards to third parties through the legal remedies provided by the Federal Acquisitions Law on behalf of the participant on the public tender. The applicable law for public acquisitions establishes an administrative remedy to contest unlawful awards.
(4) When suitable, awards can be challenged through the Amparo suit, which is a constitu-

tional action that can be brought by the titleholder of the patent in parallel to the legal remedy mentioned in section "3" above. An Amparo is a rather unique legal remedy under Mexican law, governed by a specific law, the Amparo law. It is a legal remedy available to individuals and private corporations whereby acts of authorities, whether Federal or Local, can be contested. An Amparo suit contesting acts of administrative authorities are to be filed at Federal District Courts and their decisions can be appealed before the Federal Circuit Courts.

i. In accordance with the Amparo law the parties to the proceedings of the corresponding suit are: appellant (the party filing the Amparo suit), the authority and/or authorities (those that issue the contested decision) and the so-called Third Party (the party that may be affected by the decision on an Amparo); there are Amparos where no Third Party exists.
ii. An Amparo always contests a decision of an authority that in the opinion of the party taking this legal remedy violated its Constitutional Rights. Such act (decision) of authority is called in Spanish "*Acto Reclamado*."
iii. Appellant seeks with this legal remedy to obtain a decision whereby the Federal Judge orders the authority to restore the appellant in the constitutional rights that were violated.
iv. A Federal Judge can decide an Amparo suit on its merits or dismiss it. When the decision is favorable the appellant is restored in its constitutional rights that were violated by the act of the authority. If the decision is unfavorable to appellant then the contested act of authority prevails and remains untouched. Finally, the Amparo law establishes causes for dismissing an Amparo, among them being the following, of interest for the case that will be considered in subsequent paragraphs:
    a. when the contested act of authority does not harm the legal interest of appellant.
    b. when the contested act of authority has ceased in its effects.
    c. when the Amparo suit was extemporaneously filed with the Federal Courts. For Amparo suits contesting certain acts of authority, a non-extendible term of fifteen working days is established in the Amparo law as the term within which to file an Amparo suit. Usually, this term is counted as of the day following the date on which appellant became aware of the act of authority harming its constitutional rights.

(5) Detect and challenge the validity of marketing authorizations (*registros sanitarios*) granted to third parties for patent infringing products. As mentioned below, Olivares & Cia fashioned an innovative legal action against these types of illegal marketing authorizations before the FCTA.
(6) File patent infringement actions before IMPI against the participants in public tenders with infringing products. The LIP establishes preliminary injunctions to stop the manufacture and commercialization of the infringing product.
(7) Conduct strong lobbying before IMSS and ISSSTE in order to educate them about the relevance of patent rights.

Furthermore, the Federal Acquisitions Law was amendment on May 28, 2009.

Article 31, section XXV of this law was amended to state that public entities cannot be held responsible for patent infringements.

Likewise, Article 41, Section I, was amended to establish that government entities can only acquire patented products directly when there is no "substitutes or alternatives" for the patented product.

Legally speaking, these provisions allow authorities perform a narrow interpretation. There is no official certification of non infringement patent.

We consider the provisions in mention are unconstitutional. The first one, as prior to the amendments, titleholders or licensees had the right to file infringement actions and request preliminary in-

junctions against the government agencies which acquire, store, distribute and supply patent infringing products.

The second one can be considered unconstitutional based on the following:

- Before the amendments, titleholders and licensees had the prerogative to be awarded directly and no public bid was required, with the wording of the Article now in force, prior to a direct award, it is required to look for "substitute" and "alternative" products.

- The wording of the new law provides prerogatives to the "*substitute*" and "*alternative*" products over patented products.

- Article violates Constitutional provisions of due process of law as the amendment is arbitrary when using the terms "*substitute or alternative*" "*technically reasonable products*" which are not defined.

2. Linkage System

On September 19, 2003, an amendment to the Regulations of the Health Law as well as to the Regulations of the Law on Industrial Property was enacted. The purpose of the amendment was to establish coordination rules between the Ministry of Health and the Mexican Institute of Industrial Property, in connection with the granting of pharmaceutical product registrations for marketing authorizations. The rationale behind linking these two agencies was to prevent the grant of marketing authorizations that violated exclusive rights.

On 13th January 2010 the Supreme Court issued a groundbreaking decision on the interpretation of the Linkage Regulation, which has been in force for six years. The decision focused on whether the linkage system is limited to compound patents or whether it extends to product patents that cover pharmaceutical formulations. The Supreme Court ruled that formulation patents should be listed in the Linkage Gazette, as only process patents are excluded from the regulation.

Amendment to the Health Regulation.—The reform dictates that applicants for marketing authorizations for allopathic medicines shall have the obligation to indicate if they own a patent or have a license on said product.

However, please note that the applicant for a marketing authorization has the obligation to declare under oath if they are patent owners or licensees when said patent is listed in the Linkage Gazette, so that they cannot be accused of misleading the authority, or hiding information.

In the event that applicants do not have a patent or a license, they will be required to declare under oath that the product is in compliance with the patent laws, since before granting marketing authorizations to third parties other than the title holder, COFEPRIS must also check the listed patents, first by compound and then by the list of patented products issued by IMPI in the Linkage Gazette, which is organised according to the active ingredient's generic name. COFEPRIS must also establish the possibility of requesting additional information from the applicant.

In that case, Health Authorities shall request technical assistance from the Mexican Institute of Industrial Property (IMPI), so that within a term of ten working days, this latter performs a patent clearance. If COFEPRIS requests technical assistance, IMPI then has 10 days in which to produce an opinion on the scope of the patent and whether the product for which market authorization is sought falls within.

If the search reveals that the product subject to the registration falls within the scope of any patent, the Ministry of Health shall give applicant a chance to show that it has a right to make and sell that product. In the absence of convincing evidence, the application shall be dismissed.

A generic company shall be entitled to apply for a marketing authorization for a patented medicine listed in the Linkage Gazette without having any rights to it, if the application is filed within three years for chemical products and eight years for biotechnological product before the corresponding patent expires. This provision, supported on the *"Roche Bolar Exception,"* would allow the applicant to

start safety and efficacy tests, interchangeability test, and experiments, in order to be ready to enter the market as soon as the patent has expired.

Amendment to the Industrial Property Regulation.—Such amendment imposes on the Mexican Institute of Industrial Property (IMPI) an obligation to publish a special Linkage Gazette listing those patents relating to allopathic drugs, and their correspondence to a non-proprietary name (INN). The Linkage Gazette includes products that are the subject of industrial property rights according to their active ingredients and chemical names.

Patents covering manufacturing and formulation processes are expressly excluded from this gazette.

Under the regulation, IMPI must publish and update the Linkage Gazette every six months, listing those patents in force that cover allopathic medicines and containing the following information for each patent:

- The medicament's generic name.
- A description of the medicament.
- The medicament's chemical name.
- The patent number.
- The patent's expiration date.
- The annuities paid.
- The patent owner.
- The main claims.
- Any general comments.

Products are listed in alphabetical order according to their generic name.

Authorities involved in the Linkage System include the following:

Mexican Institute of Industrial Property (IMPI).—This is the authority in charge of publishing the Linkage Gazette, which will contain patents in force that cover allopathic medicines.

Health Authority.— Is the authority in charge of granting marketing authorizations, which is the document that allows a person or entity to commercialize a pharmaceutical product.

The Health Authority is also bound to observe the Linkage Gazette, in order to prevent the granting of marketing authorizations to third parties who are not the title holders or licensees of patent rights.

Procurement Agencies (IMSS and ISSSTE).—These are the governmental entities in charge of purchasing pharmaceutical products. As it will be explained below, said authorities use the Linkage Gazette as a purchase catalogue.

IMPI's misinterpretation interpretation of the Linkage Gazette:

According to the Mexican IP Regulation, IMPI is bound to publish every six months a Gazette that includes those patents in force that cover allopathic medicines, regardless if said patents cover an active ingredient per se, or a pharmaceutical composition that comprises an active ingredient.

However, since the first Linkage Gazette was published in October 2003, it has included only patents covering compounds per se and has not included patents that cover pharmaceutical compositions and medical – use patents. We consider that IMPI has erred in its interpretation of the regulation.

Olivares and Cia, has fashioned a litigation strategy and also handled the majority of the cases, contesting this wrong interpretation through constitutional actions to obtain the publication of patents covering formulations and second uses.

The main argument we put before courts when petitioning for the inclusion of such formulations and patents in the gazette rests on the legal and technical definitions of key words in the Linkage Regulation: "allopathic medicines"; "patented products" as opposed to "process patents"; and the interpretation of "according to its active ingredient", where the active ingredient is a reference to the organisa-

tion of a list of products and not the subject matter of the list, which is not limited to patents covering active ingredients but covers allopathic medicines with patents in force or products subject to protection based on the Industrial Property Law (as literally stated by the Linkage Regulation and the full name of the Linkage Gazette, which is the Linkage for Allopathic Medicines with Patents in Force).

After eight years of linkage regulation in Mexico, the Mexican Supreme Court issued a decision on the opposing criteria held by three Mexican Circuit Courts regarding the interpretation of the linkage regulation, particularly, the dilemma of whether the linkage system is limited to compound patents or if product patents covering pharmaceutical formulations should also be listed. The Supreme Court ruled that formulation patents should be listed in the linkage gazette, in consequence, these patents should have to be observed by the Mexican Health Authority (COFEPRIS) prior to grant marketing authorizations. The following is an abstract of the Supreme Court's decision:

Case law by contradictory rulings 7/2010 Industrial Property. Patents for allopathic medicines of their claims that do not represent processes for production or formulation of drugs and which in their pharmaceutical composition include an active ingredient, substance or principle, shall be included in the publication referred to in Article 47bis of the Industrial Property Regulations. These patents must be published in the gazette, since they comply with the requirements under Article 47bis of the Industrial Property Regulations, which state that in the case of patents granted to allopathic medicines, IMPI shall publish in the gazette and shall make public a list of products that should be subject to industrial protection according to the active substance or ingredient, which shall specify the duration of the patent in question.

The Supreme Court decision will be considered as a binding precedent to all federal circuit courts and district courts in Mexico, which means that if IMPI fails to include formulation patents in the Linkage Gazette, it would be ordered to list the patent by court orders, provided that the corresponding conditions are met.

This is a landmark case, not only because of its favourable impact on patents law, but also because few cases involving the review of IP rights ever come before the Supreme Court.

Under the Supreme Court's decision, all patents covering allopathic medicines, regardless of whether they are for compounds or formulations, may be published in the Linkage Gazette. For compound patents, the only requirement is that the titleholder or its representative petition IMPI for publication, either directly or through the Chamber of Pharmaceutical Companies. However, the impact of the Supreme Court's decision on formulation patents will remain uncertain until the relevant authorities make their position clear. Legally speaking, administrative authorities such as IMPI and COFEPRIS are not bound to follow judicial case law; however, from a moral and practical standpoint, they tend to observe such precedents.

It is important to mention that the inclusion of formulation patents in the linkage gazette provides a preventive measure to avoid that the Mexican Health Authorities would grant marketing authorizations which may fall within scope of the listed patents, and, in addition, the publication provides the following benefits:

a) Prevents patent infringement;

b) It's a valuable source of information to third parties wishing to obtain authorizations for generic drugs, in order to know the full scope of opposable patents.

c) In case that the linkage gazette is not observed by Health Authorities, the publication of patents is also useful to challenge marketing authorizations for the patented formulations granted to third parties without authorization of the patent holder.

d) The Linkage Gazette is also informative in public acquisition processes, to confirm that the product to be acquired is covered by a patent, especially when the patent of formulation listed in the gazette matches with the description of the product in the National Formulary for purchases of medicines by the Mexican Government.

We always recommend to patent owners to obtain the listing in the Linkage Gazette of their formulation or use patents, especially when they expire much after the patent that covers the active ingredient *per se*.

It is worth mentioning that a Circuit Court recently ruled on behalf of a pharmaceutical company considering that such company had the proper legal standing to request COFEPRIS to observe the patent listed in the linkage gazette and requested the observance of the linkage regulation. In addition, the Circuit Court agreed with the allegation that article 167bis of the Linkage Regulation is unconstitutional as it does not provide the right of the titleholder of the patent to be heard during the approval process.

This is the first case in Mexico deciding unconstitutionality against a provision of the linkage regulation but on behalf of the patent holder.

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

3. Challenges Against Pharmaceutical Marketing Authorizations in Mexico—Breaches Against Linkage System and Data Package Exclusivity

The Mexican Linkage Regulation has been a useful tool that has opened new venues for contesting those marketing authorizations granted in violation of patent rights.

Prior to the creation of the Linkage System in Mexico, Health Authorities did not generally observe patent rights, and rather granted marketing authorizations for pharmaceutical products (compound and formulation), regardless of patent protection.

However, with the creation of the Linkage Regulation, Olivares & Cia was able to successfully obtain a landmark Court decision annulling a marketing authorization granted in breach of these regulations, in which the Court is clearly stating that Health Authorities are bound to observe patent rights.

The Linkage Regulation has proved to be the best legal mechanism to prevent the violation of patents covering medicines. In addition, along with the corresponding regulatory requirements for generic approvals by proving safety and efficacy through interchangeability test with the product of reference (sometimes the innovator product) are of high value to prove prima facie the imminent violation of the linkage regulation and/or the patent/s in force as although the generic´s dossiers are confidential, the applications for generic medicines are published in the official web site of COFEPRIS, including the name of the applicant, the generic name of the active ingredient, the pharmaceutical form.

Even though, the information of the generic´s application published in the official site is very limited, if the product of reference is an innovator product, namely: a patented product and the corresponding patents are included in the gazette, there is an assumption that the generic proving safety and efficacy through interchangeability tests with the innovator product (product of reference), by law, the generic product should be bioequivalent with the innovator (patented product), therefore, there may be a legal and prima facie assumption that the generic product falls within the relevant patents covering the product of reference and listed in the linkage gazette.

The legal assumption that the applied generic product matches or falls within the scope of the listed patents in the linkage gazette, provides the grounds to file legal actions to prevent the granting of the generic approval or to have more information of the generic application and confirm whether or not the approval may violate the linkage regulation and/or a valid patent.

Marketing authorizations granted prior to the enactment of linkage regulations or in breach of patents that have not been published in the linkage gazette

In this event, even though there is no specific provision forbidding health authorities from granting authorizations in breach of unpublished patents, Olivares & Cia has assisted IP holders in bringing challenges before Administrative Courts.

In these cases, the main argument relies on the general obligation by authorities to comply with the provisions of Federal Laws, and in the understanding that, for an IP system to properly function, the authorities should not grant applicants an authorization to infringe IP rights.

Marketing authorizations granted in breach of data package exclusivity (DPE)

In previous years in Mexico the domestic law was silent in the recognition of Data Package Exclusivity (DPE) rights. However, in January 2008, the Mexican Health Regulations were amended concerning generic medications, eliminating the requirement to prove safety and efficacy for generics, which was substituted by the need to prove interchangeability.

In 2008 the regulations were modified to implement an abbreviated approval procedure for generic drugs, on the basis of bioequivalence and bioavailability studies, without setting forth any provisions containing a non-reliance period as established in the international treaties such as NAFTA and TRIPS.

Based on the hierarchy of international treaties established in the Mexican Constitution, where international treaties approved by the Mexican Senate supersede Federal Laws, our firm structured a litigation strategy to secure recognition of DPE rights in Mexico. Although we have obtained valuable preliminary injunctions, ordering the regulatory agency to refrain from grant marketing authorizations relying directly or indirectly in the dossier of the innovator or the so-called product of reference, these cases remain under prosecution and are pending to be decided on their merits by the courts.

There is no specific body of legislation referring to regulatory exclusivity in Mexico, but there are some provisions applicable to the issue, in our IP Law, the Health Law Regulations, New Molecules Regulations and International Treaties subscribed by Mexico such as NAFTA and TRIPS.

The Mexican Industrial Property Law (IPL) provides as follows:

"Art. 86bis. The information required by special laws to determine the safety and efficacy of pharmaceutical and agricultural chemicals that make use of new chemical compounds shall be protected in terms of the international treaties which Mexico has signed."

The Health Law Regulations provides as follows:

"Art. 167 Bis.-

…

The information referred to in Articles 167 and 167bis of this Regulation which is confidential or reserved in accordance with the provisions of international treaties to which Mexico is party and with other applicable laws, shall be protected against any disclosure to third parties."

On the other hand, applicable International Treaties, such as NAFTA and TRIPS, state the following regarding data protection:

> NAFTA: Undisclosed information submitted to obtain marketing authorizations shall be protected from being disclosed to, or relied upon by third parties, for at least 5 years.

TRIPS: Information provided to obtain a marketing authorization must be protected, and cannot be disclosed to third parties.

It is important to point out that, according to firm jurisprudence, these treaties are applicable in Mexico above our Federal and Local Laws as long as they don't go against the Constitution.

Olivares & Cía. devised, structured and executed a legal strategy to obtain the recognition of DPE for products that deserve this protection, obtaining the only two legal precedents by a court of law, recognizing and ordering the agency in charge to grant marketing authorizations to observe and recognize DPE.

On June 19, 2012, COFEPRIS published in their official website an internal decree providing guidelines to observe and protect DPE in Mexico with the following main principles and considerations:

* Information submitted in a process of regulatory approval is protected against unfair commercial use and disclosure.
* Five years maximum protection. During this period of time, no one can use information provided by the innovator for the commercialization of the drug.
* COFEPRIS would grant approvals for generics once the five years of protection lapses, unless the generic drug proves safety and efficacy independently.
* Protection for undisclosed and unpublished experiments and information, with the exception for publication of data necessary to protect the public or when confidentiality measures have been taken to protect unfair commercial use.
* Protection provided for new chemical entities only and for the information and data provided to prove safety and efficacy.
* The gathering of the data involves considerable research efforts.

These guidelines demonstrate that COFEPRIS recognizes and protects DPE pursuant to NAFTA and TRIPS and there is no doubt that the decree is positive as it provides a higher degree of confidence to innovators; however, certain issues are not clear and require further clarification, i.e. would the guidelines apply to biological products? There are other approvals which require considerable efforts such as new formulations and indications; are they protected? The decree is also silent about the proceedings and measures to enforce and observe DPE rights, providing uncertainty to all the involved parties.

The main question and test will be the weight and strength of an internal decree versus the lack of domestic statutory law recognizing DPE. According to our legal system and taking into consideration that this decree can be disregarded or changed by an eventual new administration of COFEPRIS after the coming Presidential elections, Olivares & Cia efforts and suggestions will continue focused to obtain a clear and specific regulation of DPE in the statutory law or regulation.

Olivares & Cia developed a litigation strategy that could be attempted by the affected party in case of a breach of DPE, as follows.

a. Actions Against the Authority in Charge of Issuing Marketing Authorizations

The main available venue for enforcement of the exclusivity rights against an act of authority is the Nullity Trial before the Federal Court of Administrative Affairs. In this trial, the action is brought against COFEPRIS, accusing said breach as a violation of the above-mentioned provisions. The object of this Trial would be a revocation of the marketing authorization.

In this action, the affected party can request the court to provide a copy of the dossier that is ac-

cused of containing information obtained in breach of data exclusivity, and the court can take one of the following positions concerning this dossier:

- The court can decide that the dossier can be accessed by the challenging party, which will have an obligation of confidentiality concerning the corresponding information. This confidentiality will include a prohibition for using this information in an eventual patent infringement action.
- The court can determine that the information will not be accessed by the challenging party, but only by the court and its appointed expert.

If the third party's dossier indicates that there was a disclosure of information provided in the innovator's dossier, there would be a clear-cut case for the annulment of the marketing authorization based on existing provisions in our laws.

On the other hand, if there was no disclosure, but only reliance on information that remains confidential, the action would have to be based on a breach of obligations in International Treaties, and an eventual constitutionality challenge against the provisions in our laws that do not contemplate data exclusivity, specifically those concerning generic applications.

As additional venues, an affected party could bring a specific criminal or civil action against the officer responsible of the disclosure, which should of course be analyzed on a case by case basis.

b. Actions Against the Third Party Using the Information Obtained in Breach of Data Exclusivity

Actions against this third party have to be determined on a case-by-case basis, since the use of the information contained in the original marketing authorization in its entirety could provide basis for a copyright infringement action, an action for unfair competition, or a criminal action for the purposeful obtainment or use of confidential information.

It is important to point out that the enforcement of data exclusivity has been sought by Pharmaceutical Companies through the above-mentioned venues, however this is a relatively new field in the Mexican Legal System and thus, so far there are no specific precedents indicating any of these venues as correct.

4. Conclusions regarding Linkage Regulation.

The Mexican Legal System has been advancing in its adaptation to modern IP Systems, especially through the establishment of Linkage regulations establishing coordination between Health and Patent authorities in our country. This has allowed for IP rights holders to bring actions, some successful, others yet to be decided upon, enforcing these rights, and questioning the actions of Health authorities, which is a clear improvement from the mere possibility of requesting declarations of patent infringement.

The decisions obtained by our firm annulling a marketing authorization for breach of the Linkage System have surely set favorable precedents for IP holders in Mexico, for all pharmaceutical patents.

Finally, it is worth mentioning that while we were updating this article, the North American Free Trade Agreement (NAFTA), the European Free Trade Association (EFTA) and the European Union Free Trade Agreement between Mexico are being reviewed, renegotiated and modernized; there is a grade of uncertainty about the final outcome of the renegotiation, but it is expected that the modernization of said treaties would impact in a positive way the Intellectual Property system in Mexico.

The main issues in the renegotiation of these treaties are:

- Non-traditional trademarks.
- Madrid Protocol/International trademark applications.

- Appellation of origin and geographic indications.
- Efficient and prompt civil and criminal enforcement.
- Effective customs measures
- Pharmaceutical patents. (patentable subject matter, patent term extensions, linkage, exhaustions of rights and regulatory exceptions to patent infringement)
- Agrochemical patents.
- Data Package Exclusivity for medicaments and agrochemicals.
- Copyrights and the digital era.