IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NORTH AMERICAN FREE TRADE AGREEMENT

AND THE UNCITRAL ARBITRATION RULES (1976)

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

EXPERT REPORT OF HEDWIG LINDNER

JANUARY 26, 2015

Trade Law Bureau
Departments of Justice and of Foreign Affairs, Trade and Development
Lester B. Pearson Building
125 Sussex Drive
Ottawa, Ontario
K1A 0G2
CANADA

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A. INTRODUCTION

1. Background and Qualifications

1. I have been practicing intellectual property law in Mexico since 1989. I studied Law at the Universidad Panamericana in Mexico City, and graduated with honors in 1989. I received a post-graduate degree in extraordinary constitutional procedures (*amparo* proceedings) from the former Institute of Judicial Specialization of the Supreme Court of the Nation (now the Institute of Federal Judiciary) (1990). I also hold a Master's Degree in Constitutional and Administrative Law from the National Autonomous University of Mexico (UNAM) (1991-1993), and a Master's Degree in Intellectual Property Law from George Washington University in Washington D.C. (1993-1994). I am currently pursuing my Doctorate at the Universidad Panamericana.

2. I am a Lecturer at Universidad Panamericana where I teach graduate level business law courses.

3. I am one of the founding partners of Arochi & Lindner, S.C. (A&L), an intellectual property law firm with offices in Mexico City, Barcelona and Madrid. Since its establishment in 1994, A&L has become recognized as one of the premier intellectual property law firms in Mexico. A&L has been rated a top-tier ("Band 1") firm in Chambers & Partners' publication *Chambers Latin America*, in 2011, 2012, 2013, 2014 and 2015.

4. My practice includes all types of intellectual property litigation, with a focus on pharmaceutical patents, and since 1996 I have been involved in a number of high profile pharmaceutical patent cases. I am counsel to the National Association of Medicine Manufacturers (ANAFAM in Spanish)[1]. During the entire legislative process that preceded the 2010 reforms to the Industrial Property Act (IPA),[2] I participated as an industrial property expert, advising ANAFAM, which decided to support the 2010

[1] ANAFAM represents the most important businesses in Mexico which are mainly privately-owned Mexican companies. These businesses are important suppliers of medication to the health system and the private market. Accessed on 10 December 2014. See online: <http://www.anafam.org.mx/quienes.htm> (**R-137**).

[2] Industrial Property Act, Official Diary of the Federation of June 27, 1991, Current text (Last Reform, Official Diary of the Federation of April 9, 2012) [IPA] (**R-202**).

Reform initiative. I have been invited to join the private delegation that accompanies Mexican negotiators to the negotiation rounds and meetings of the Intellectual Property Chapter of the Trans-Pacific Partnership Agreement (TPP).

5. I have written various articles for a number of publications, including most recently: "Recognizing Equivalence, Reciprocity and Respect" (*Life and Sciences Intellectual Property Review*, 2011); "A Question of Fairness: Preliminary Injunctions in Mexico" (*Life and Sciences Intellectual Property Review*, 2012) and "More Muscle: New Data Protection Guidelines in Mexico" (*World Intellectual Property Review*, November/December 2012). In Mexico, I recently published: "*Medicamentos genéricos y medicamentos patentados: una disputa no resuelta*" in OROPEZA GARCÍA, Arturo and GUÍZAR LÓPEZ, Victor Manuel (coordinators): "*Los retos de la industria farmacéutica en el siglo XXI. Una visión comparada sobre su régimen de propiedad intelectual"* (Universidad Nacional Autónoma de México, Institute of Legal Investigations, COFEPRIS, Mexico, 2010) and "*Procesos de innovación y patentes farmacéuticas en el marco del Acuerdo de Asociación Trans-Pacífico (Trans-Pacific Partnership Agreement, TPP)*" in OROPEZA GARCÍA, Arturo (coordinator); "*El Acuerdo de Asociación Transpacífico ¿Bisagra o confrontación entre el Atlántico y el Pacífico?"* (Universidad Nacional Autónoma de México, Institute of Legal Investigations, CEPAL, Mexico, 2013).

6. In addition to having been the President of the Mexican Chapter of the International Association for the Protection of Intellectual Property (AIPPI) from 1998 to 2001, I am active in several other intellectual property organizations, including the Mexican Bar Association, the International Trademark Association (INTA), the Inter-American Intellectual Property Association (ASIPI), and the American Intellectual Property Law Association (AIPLA). I served on the Editorial Technical Council on Piracy and Counterfeiting of *Reforma*, a leading Mexican daily newspaper (2013-2014).

7. I have been recognized on several occasions as a leading Intellectual Property lawyer by various publications, such as *Managing Intellectual Property*, *Chambers Latin America, Chambers Global, World Trademark Review 1000, IAM Patent 1000, Who's*

Who Legal, Latin Lawyer 250, and the *Legal 500 Latin America Guide*. I am listed as an expert in patent law in the *Best Lawyers Guide*.

2. Mandate

8. I have been asked to provide my legal opinion concerning issues addressed by the Claimant regarding Mexican patent law, and in particular concerning the following:

1) The nature of the reforms made to the Mexican legal system as a result of the entry into force of NAFTA;
2) the nature of the reforms to Mexican patent law since 1994, and in particular the 2010 reform;
3) the effects of these reforms, in particular the 2010 reform;
4) the extent to which the IPA addresses matters such as speculative patenting / over-claiming ;
5) the patentability criteria regarding selection inventions and pharmaceutical patents with generic claims;
6) the institutional context of Mexican patent law, as well as its effects on the granting of patents and the related invalidation proceedings in the Mexican system; and
7) the validity of the Claimant's patents (equivalent to the Canadian patents at issue in this proceeding) under Mexican law.

9. My expert report is filed in Spanish, and it is accompanied by an English translation. In the event I have to provide live testimony, my intention is to do so in Spanish.

10. The views and opinions contained in this report are my own and are totally independent of the Government of Canada. Additionally, I should note that, in an unrelated matter, I represent a Mexican laboratory sued by Eli Lilly in ongoing litigation before Mexican tribunals. This proceeding does not raise the same issues as those addressed in the present report, and I confirm this other retainer has had no impact on the content of my opinion.

3. Synopsis

11. Mexican patent law has been developed through a series of legislation and legal reforms. The most notable are the Act of 1991 (Promotion and Protection of Industrial Property Act (PPIPA)),[3] the reform of 1994, and the reform of June 18, 2010. The reform of 1994 (which implemented NAFTA) did not modify the substantive requirements of patentability. In fact, with respect to substantive modifications relating to patents, the most important was the reform of June 18, 2010. The legislative process for the 2010 reform shows that the legislators clearly recognized the necessity of improving the definition of industrial applicability.[4]

12. Industrial applicability is a substantive requirement that, like novelty and inventive step, must be met by patent applicants in Mexico. While the Mexican Institute of Industrial Property's (IMPI) examiners do not often expressly object to a patent due to a lack of industrial applicability, they do for lack of clarity or insufficiency in the description, which in many cases effectively denotes a lack of industrial applicability. I am not aware of any case in which Mexican tribunals had to interpret the concept of industrial applicability. Due to institutional limitations, few patent cases come before Mexican courts. Nevertheless, should such a case arise, the tribunals would have to provide an interpretation that is coherent and in line with the IPA and the Congressional Declaration of Purpose of the 2010 reform.

13. With the passage of time, the material and human resources of IMPI have improved. When IMPI was created (1994), it lacked sufficient resources in terms of the number of examiners, their training, and their education. As a result, in the 1990s the majority of patent applications filed in Mexico were granted almost automatically, provided that the applicant showed that the equivalent patent had been granted abroad. This practice has been changing gradually, leading to a significant increase in the number

[3] Promotion and Protection of Industrial Property Act, Official Diary of the Federation of June 27, 1991 (**R-275**)

[4] Congressional Study of the United Commissions of Commerce and Industrial Development, of Health and Legislative States, Second, which contains the Decree regarding the Industrial Property Act (Mexican Senate) Official Diary of the Federation of December 9, 2009 [Congressional Study – Senate- 2010 Reform], p. 5 (**R-276**).

of administrative decisions regarding patentability requirements issued and the quality of patent examinations.

14. Patent MX173791 (olanzapine) and patent MX202275 (atomoxetine) have not been challenged in Mexico. I disagree with the Claimant in its conclusion that the two patents if challenged would be found valid. Mexican patents MX173791(olanzapine) and MX202275 (atomoxetine) were evaluated with low technical rigor, and they should have been the subject of objections, which, if not overcome by the applicant, should have led to the patents being rejected. In Mexico it is rare for patents to be challenged due to the complexity of litigation, its high cost, the time it takes to resolve litigation, the particularities of the Mexican legal system and the unpredictability of decisions rendered by Mexican judges lacking experience in patent law. Thus, no definite conclusion may be drawn from the absence of any litigation challenge to these two patents in Mexico.

B. ANALYSIS / DISCUSSION

1. The Nature of the Reforms Made to the Mexican legal system as a Result of the Entry into Force of NAFTA

15. In January 1994, NAFTA came into effect. The implementation of NAFTA did not require any modification or adaptation of the substantive requirements of patentability under the IPA. In fact, the really substantial change in Mexican law, at least with respect to patents, occurred before NAFTA, through the adoption and publication of the PPIPA.

16. The introduction of the Congressional Declaration of Purpose for PPIPA[5] states that the future enactment of PPIPA is framed within the ambit of the National Plan of Development 1989-1994 (NPD).[6] The fundamental objective identified in the NPD was to introduce a rapid and effective technological modernization of the national system of production.

[5] Congressional Declaration of Purpose about the PPIPA, Official Diary of the Federation of December 6, 1990 (initiative of the executive) [Congressional Declaration about the 1991 Act] (**R-277**).
[6] National Plan of Development 1989/1994, Decree 31-05-89 [NPD] (**R-278**).

17. As a consequence, the principal objectives of PPIPA concerned access to patents through the elimination of impediments to patenting in certain areas (such as pharmaceutical products, medication in general, drinks and food for animal consumption, and chemical products);[7] decriminalization of patent infringements in order to classify them as administrative infractions (rather than criminal offenses); and the increase in the term of patents in Mexico from 14 to 20 years.[8]

18. In 1994, PPIPA was reformed ("the reform of 1994"),[9] in the context of the entry into force of NAFTA.[10] As part of the reform, PPIPA changed its name and became known as the IPA.

19. The Congressional Declaration of Purpose of the reform of 1994 does not mention that the objective of the reform was the harmonization of IPA with its equivalent in the United States or Canada.

20. The reform of 1994 did not modify the substantive requirements of patentability. Requirements stated in NAFTA such as novelty, inventive step (or non-obviousness) and industrial applicability (or utility) already existed in the three jurisdictions of the Parties. NAFTA did not impose any definition of these criteria which the Parties would be obliged to insert into their national legislation. Consequently, the Parties may, in the exercise of their sovereignty, give meaning to these undefined or undetermined legal concepts.[11] Additionally, the text of NAFTA left flexibility in its implementation for Parties to use, at their discretion, different basic terms reflecting their respective domestic

[7] Congressional Declaration about the 1991 Act; p. 6 (**R-277**).
[8] Congressional Declaration about the 1991 Act indicates that "In Chapter II of the Second Title, it is proposed that the patent term be for twenty years from the date of presenting the patent application, and not for fourteen years from the grant of the patent, as currently stated in the law."; p. 7 (**R-277**).
[9] Decree that reforms, adds, and repeals several articles of the Law of Development and Protection of Industrial Property are reformed or new articles are added, Official Diary of the Federation of August 2, 1994 [Decree of August 2, 1994] (**R-279**).
[10] Congressional Declaration of Purpose that reforms, adds, and repeals several articles of the PPIPA, Official Diary of the Federation of June 29, 1994 (initiative of the executive) [Congressional Declaration about the 1994 Reform] (**R-280)**.
[11] In this respect, see the Jurisprudence of Judicial Power of the Federation 46/2007; p. 2472 (**R-281**).

legal system (e.g. “industrial applicability” in Mexico, or “utility” in the United States and Canada).[12]

21. In practice, the inherent flexibility provided in NAFTA has resulted in differences between the patent laws of these three partner nations.

22. The IPA, for example, does not permit the patenting of surgical methods, whether for treatment or diagnosis (as is allowed in the U.S.). It also does not recognize patent term extensions for unjustified delays in granting patents or for delays in granting health related authorizations necessary for the marketing of pharmaceutical products protected by patents.

23. There are also differences in the evaluation of novelty. In Mexico, a document affects novelty only when it explicitly divulges the claimed invention, whereas it is my understanding that in the United States, a document that implicitly divulges an invention may also affect novelty (inherency doctrine).

24. On the other hand, for the determination of the requirement of inventive step in Mexico, one cannot simply evaluate whether the invention could or could not be obvious given the state of the art. There must also be experimental evidence in the patent application to support the presence of an unexpected effect. It is also my understanding that in the United States, for the evaluation of the requirement of “non-obviousness” one can take into account commercial success and the time it took before a specific need was addressed, while in Mexico these factors are not considered relevant.

25. Few NAFTA provisions required implementation into the IPA and those that did, were mostly procedural and motivated by the differences that exist between the Anglo-Saxon (common law tradition*)* legal system and the Roman-Canonic legal system (civil

[12] Article 1709, paragraph 1 of NAFTA states that Parties shall grant patents for any inventions, in all fields of technology, provided that such inventions "are new, result from an inventive step and are capable of industrial application". Each Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful" respectively —this recognizes that the Parties may or may not consider such expressions as synonymous at their discretion.

law tradition),[13] such as the imposition of precautionary measures in proceedings for the administrative declaration of an infringement (Articles 199 Bis through 199 Bis 7)[14]; the possibility of requiring evidence or information held by third parties including the presumed infringer (Article 192 Bis); and the reversal of the burden of proof in cases of infringement of process patents (Article 192 Bis 1). In addition to these procedural changes, Article 78 of the IPA was also amended to include Article 47 of the IPA as a basis upon which a patent may be declared invalid. At that point, the obligation to include a sufficiently clear and complete description of the invention became a necessary and essential element of patent applications. This particular change was not required by NAFTA (which does not address disclosure issues) but it did provide an important clarification to Mexican patent law.

26. The 1994 reform also confirmed the patentability of every type of invention that meets the requirements of novelty, inventive step and industrial applicability, expressly excluding only a limited number of inventions (Article 16)[15]; eliminated the extensions specific to pharmaceutical patents (Article 23)[16]; and specified the type of rights that product and process patents confer (Article 25).

[13] In this regard, in the Congressional Declaration of Purpose of the 1994 Reform, it was stated that "[i]n light of the fact that the commercial exploitation of a patented product or process does not depend exclusively on the granting of a patent, but rather on other factors such as the authorization by other governmental authorities or by the owners of other patents, patents rights are defined in the light of the actions that third parties cannot perform without the consent of the patent owner", pp. 6 and 7 (**R-280**).
[14] On this point, in the Congressional Declaration of Purpose of the 1994 Reform, it was established: "In this sense, the initiative proposes to equip the authority with the power to order the suspension or termination of the actions that presumably violate a right of intellectual property, such as the withdrawal from circulation of the infringing merchandise […]", p. 5 (**R-280**).
[15] The Congressional Declaration of Purpose of the 1994 Reform indicates that "The dynamism and the complexity of the field requires certainty, and the present initiative, if adopted, would specify which inventions are excluded from patentability and, consequently, all other inventions—which are not listed—will be patentable."; p. 2 (**R-280**).
[16] With respect to the Congressional Declaration of Purpose of the 1994 Reform, it was stated that "[w]ith the purpose of eliminating any discriminatory condition or different treatment between nationals and foreigners, it is proposed to suppress the three year extension to the patent term in cases where the owner of the patent grants a license to a business with privately-owned capital in Mexico."; p. 6 (**R-280**).

2. The Nature of the Reforms to Mexican Patent Law Since 1994, and in Particular the 2010 Reform

27. Since its publication, the IPA has been reformed various times.[17] These reforms covered a variety of topics.[18] In the area of patents, the most important was the reform published in the Official Diary of the Federation on June 18, 2010 (reform of 2010).[19]

28. In their testimony, Mrs. Gilda González and Mr. Fabián Salazar suggested that the 2010 reform was without merit and unnecessary.[20] I disagree with this view. In fact, as evidenced by the Congressional Declaration of Purpose,[21] the Studies of the Commissions, and the Discussions in the Senate of the Republic, the legislators at all times believed that the proposed reforms were necessary to achieve a balance between promoting creativity and innovation;[22] maintaining the balance between free competition and innovation, and between public and private interests;[23] ensuring the evaluation of

[17] Reforms to the Law of Industrial Property (previously the Law of Development and Protection of Industrial Property); published in the Official Diary of the Federation: August 2, 1994; October 25, 1996; December 26, 1997; May 17, 1999; January 26, 2004; June 16, 2005; January 25, 2006; May 6, 2009; January 6, 2010; January 6, 2010; June 18, 2010; June 28, 2010; January 27, 2012; April 9, 2012.

[18] The reforms that the Law of Industrial Property underwent covered several themes. For example, the reform of December 26, 1997 established the regulation of layouts for the designs of integrated circuits; the reform of May 17, 1999 modified some issues related to crimes against intellectual property; the reform of January 26, 2004 modified the scheme for licensing public utilities related to pharmaceutical patents; the reform of June 16, 2005 established a new regime for well-known and famous trademarks; and the reform of January 25, 2006 created a new legal regime for contracting franchises.

[19] Decree that reforms several articles of the Industrial Property Act, Official Diary of the Federation of June 18, 2010 [Decree of June 18, 2010] (**R-282**).

[20] Witness Statement of Gilda González Carmona, para. 22; and Witness Statement of Fabián Ramón Salazar, para. 31.

[21] Congressional Declaration of Purpose of the Initiative with Decree Project that reforms several articles of the Law of Industrial Property, presented by Senators María de los Ángeles Moreno Uriegas, Carlos Lozano de la Torre and Ramiro Hernández García of the Parliamentary Group of the Institutional Revolutionary Party, Senate Gazette of March 26, 2008 [Congressional Declaration of Purpose of the 2010 Reform] (**R-283**)

[22] Congressional Declaration of Purpose of the 2010 Reform: "The administrative normality in the area of intellectual property should have, amongst its objectives, the search for equilibrium between the promotion of creativity and innovation. This promotion is achieved by granting the rights of exclusive exploitation of a product when it is considered an invention (understood as all human creation which transforms matter or energy existing in nature, in order to satisfy concrete human needs) and the transfer and appropriate access to new technologies, so that the public interest prevail over the commercial"; Congressional Declaration of Purpose, p. 2 (**R-283**).

[23] Congressional Declaration of Purpose of the 2010 Reform: "Unfortunately, the balance between free competition and innovation and between general and particular interest that relies on the legal patent regime, on occasion is lost to the detriment of society. Thus patents depart from their role as promoter of innovation", p. 2 (**R-283**).

patent applications;[24] reducing abuses in the exercise of patent rights;[25] complying with international obligations;[26] and re-establishing the balance between the various objectives of the patent system.[27]

29. The 2010 reform modified substantive as well as procedural provisions of the IPA. Among the substantive modifications was the addition of the term "practical utility" and the phrase "for the purposes described in the application" (Article 12) to the definition of "industrial applicability". The 2010 reform also modified the description requirement by adding an obligation to include information that exemplifies the industrial applicability of the invention (Article 47).

30. In this regard, the Congressional Declaration of Purpose stated that, in practice, the industrial applicability requirement had been undermined since "frequently there are patent applications in which the applicant does not define with precision the utility of the invention, which is then overlooked when the other two requirements [novelty and inventive step] are met."[28] The Congressional Declaration of Purpose also adds that "deferring the definition of industrial applicability to subsequent stages of the examination of the application may lead to […] [running] the risk of granting weak patents that then become obstacles for parallel or future developments."[29]

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[24] Congressional Declaration of Purpose of the 2010 Reform: "It is for this reason that the legislation in the area has contemplated mechanisms that guarantee that the granting of patents is based on a precise analysis, that addresses the equilibrium between the incentive that is granted to the inventor (or its successor), and the effects on society in terms of competition."; Congressional Declaration of Purpose, p. 4 (**R-283**).

[25] Congressional Declaration of Purpose of the 2010 Reform: "In this context, the present initiative coincides with the international tendency of finding mechanisms that reduce the negative effects of the abuse in the exercise of patent rights, so that patents provide the greatest benefit possible for the general interests of society.", p. 6 (**R-283**).

[26] Congressional Declaration of Purpose of the 2010 Reform: "The reforms herein proposed are inserted into the framework of the treaties to which Mexico is a Party. They do not result in the breach of Mexico's international commitments; on the contrary, these reforms try to take advantage of the flexibilities present in such treaties; flexibilities that other countries have taken advantage of and that Mexico also should use for its benefit."; Congressional Declaration of Purpose, pp. 3-4 (**R-283**).

[27] Congressional Declaration of Purpose of the 2010 Reform: "In summary, these reforms seek to reestablish the equilibrium between the many values that inform our patent system, in strict compliance with Mexico's international commitments. The goal is to create a regime that favors and rewards creativity and prevents and combats those practices which can affect the national development, which urgently require efficient and appropriate access to new knowledge.", p. 10 (**R-283**

[28] Congressional Declaration of Purpose of the 2010 Reform, p. 4 (**R-283**).

[29] Congressional Declaration of Purpose of the 2010 Reform: "The way to achieve this is to make sure that a patent only rewards the inventors that deserve it, by establishing legal requirements to grant it, which are

31. The original text of section IV of Article 12 and of section I of Article 47, proposed in the 2010 reform initiative is as follows:

> *Article 12.- For the purpose of this title will be considered:*
> *...*
> *IV.- Industrial applicability, the fact that an invention solves or helps solve in a practical way a specific problem or addresses a particular situation and can be produced or used in the industry, in commerce or in any other field of economic activity for the purposes described in the application;*
>
> *Article 47.- A patent application shall include:*
> *I. The description of the invention, which shall be sufficiently clear and complete so as to enable the full understanding of the invention and, if relevant, to guide its performance by a person with ordinary skills in the art. The invention shall also include the best-known method by the applicant to carry out the invention when this is not clear from the description of the invention, as well as the information that establishes the industrial applicability of the invention.*

32. In this regard the legislators proposed "to recover and re-evaluate the fulfillment of this fundamental requirement (industrial applicability), as well as to avoid the practice of prematurely presenting patent applications in order to secure a filing date,[30] with full knowledge that the corresponding research and development had not been concluded. This practice undermines the purpose of the industrial applicability requirement and encourages a practice that, instead of focusing on the full development of inventions, encourages the submission of unsupported applications, with the hope of perfecting them while the patent application is being processed, which ultimately alters the aim of the patent system."[31]

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known by everyone and are strictly observed. The requirements required in practically the whole world are novelty, inventive step and industrial applicability. […] The third requirement, industrial applicability, is related to the function of the invention. In other countries this requirement is given the name "utility" and justly suggests that the invention desired to be patented generates a concrete and defined benefit from the moment that it is conceived." […] "The Reform will encourage specific, clear and sufficient descriptions and claims, so that a POSITA be able to carry out the invention and improve it at the end of the patent term, renewing and refining the technology being of the purposes of the international industrial property system.", p. 4-5 (**R-283**).

[30] Congressional Declaration of Purpose of the 2010 Reform, pp. 3-5 (**R-283**).

[31] Congressional Declaration of Purpose of the 2010 Reform, p. 5 (**R-283**).

33. The Initiative was commissioned by the United Commissions of Commerce and Industrial Development, of Health and the Second Commission of Legislative Studies of the Mexican Senate. The Study of the Commissions established that industrial applicability is the function of the invention, namely the practical utility of an invention to resolve a specific problem or address a specific situation, and it is, together with novelty and inventive step, one of the requirements that make an invention "patentable" (Article 16).[32]

34. The initial definition proposed in Article 12, paragraph IV would have required inventions to solve or "help" solve a technical problem. The Commissions found that this requirement would have introduced a subjective element to the evaluation of industrial applicability. The Commissions noted that since the proposed definition did not provide the parameters to establish the degree of "help" required for an invention to be patentable, this would create uncertainty in the industrial property system.[33]

35. For this reason, the Commissions decided to modify the definition initially proposed, and adopted the following phrasing:

> "*Article 12.- For the purpose of this title, will be considered:*
> *…*
> *IV.- Industrial application, the possibility that an invention has a practical utility or can be produced or used in any field of economic activity, for the purposes described in the application;*"

The Commissions considered that the inclusion of the term "has a practical utility" would account for the need to foresee such utility without introducing elements that could result in discretion or generate confusion.[34] Additionally, the Commissions noted that the final addition to paragraph IV "for the purposes described in the application" would achieve the goal of the reform, which seeks to limit the practice of presenting patent applications to ensure a filing date, without having completed the development of industrial applicability and specified the utility of the invention in the patent application.[35]

[32] Congressional Study – Senate- 2010 Reform; p. 5. (**R-276**)
[33] Congressional Study – Senate- 2010 Reform; p. 5. (**R-276**)
[34] Congressional Study – Senate- 2010 Reform; p. 5. (**R-276**)
[35] Congressional Study – Senate- 2010 Reform; p. 5. (**R-276**)

36. With respect to the modifications to section I of Article 47 of the IPA initially proposed in the 2010 reform initiative, the Congressional Study of the Commissions noted that this requirement was already provided for in Article 28 of the Regulation of the IPA (RIPA),[36] and made the following observation: "*a description should be complete; include the best-known method by the applicant for practicing the invention; where appropriate, this indication should be done through practical examples or specific applications of the invention; as well as indicate, where relevant, the form in which it can be produced or utilized or both.*"[37]

37. Having considered the similarities between the proposed modifications and Article 28 of the RIPA, the Commissions opted for an alternative phrasing:

> *Article 47.- That the patent application shall include:*
>
> *I. The description of the invention, which shall be sufficiently clear and complete so as to enable the full understanding of the invention and, if relevant, to guide its performance by a person with ordinary skills in the art. The invention shall also include the best-known method by the applicant to carry out the invention when this is not clear from the description of the invention, as well as the information exemplifying the industrial applicability of the invention.*

The Commissions believed that the inclusion of the term "exemplify" in Article 47 of the IPA was appropriate given the objectives of the 2010 Reform[38].

38. Throughout this legislative process, it can be emphasized that the Mexican legislators always had the clear intention of improving the definition of industrial applicability, so that it be possible for this requirement of patentability to recover its central role in the granting of patents.

39. Another article that was added by the 2010 reform is Article 52 Bis, which provides for the participation of third parties in patent applications. Article 52 Bis was approved with the following text:

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[36] Regulation of the Industrial Property Act, Official Diary of the Federation of November 23, 1994, Current text (Last Reform, Official Diary of the Federation of June 10, 2012. (**R-284**)
[37] Congressional Study – Senate- 2010 Reform, pp. 8-9. (**R-276**)
[38] Congressional Study – Senate- 2010 Reform, p. 9 (**R-276**).

"Article 52 BIS.- Within a period of six months, beginning on the date of publication in the Gazette, the Institute may receive information from any person, relating to whether the application complies with what is described in Articles 16 and 19 of this Law."

40. This reform was supported by the fact that "clarity in the process for granting patents on the part of the authority and the possibility for individuals to have a more active role are important elements of a more efficient, transparent and just system."[39] However, the mechanism established in Article 52 Bis of the IPA apparently has not been used often. This could be due to the fact that in Mexico, pending patent applications are confidential. Therefore, contributions by third parties can at best be speculative in the majority of cases. As a result, there is no efficient procedure in place for third parties to challenge the validity of patent applications in Mexico.

3. The Effects of the Reforms, in Particular the 2010 Reform

41. Before the reform of 2010, the IPA contained an incomplete legal framework that was less robust with respect to the requirement of industrial applicability. That situation led to a failure by examiners to sufficiently evaluate this requirement. I believe that the reform of 2010 reaffirms that industrial applicability is, and has been, a substantive requirement that the applicant must satisfy in order for the relevant invention to be patentable.

42. Even though industrial application, as a substantive requirement, already existed before the reform of 2010, this reform made it clear that it is a requirement that cannot be avoided. This requirement is especially important in fields such as pharmaceuticals in which industrial applicability is not comparable to other areas such as mechanics. In the latter, the use of some advantage or solution to a previously stated technical problem can be adequately supported with relative ease given that the variables involved in a mechanical device or system are fewer, unlike the variables involved in biological systems.

43. By contrast, the advantages of an invention in the pharmaceutical field cannot be corroborated with ease given that the invention generally interacts with more complex

[39] Congressional Declaration of Purpose of the 2010, p. 3. (**R-283)**.

systems than the systems in the mechanical field, such as a cell or the human body. Thus, it is necessary to provide examples to show that a pharmaceutical invention is able to produce the effect set out in the description.

44. In pharmaceutical inventions, precisely due to their interaction with the human body, the requirement of industrial applicability requires the patent applicant to provide detailed information to support the claimed invention. Consequently, it is always necessary to present examples in the form of data, findings or experimental information in which the completion of this requirement is shown.

45. In the case of an active compound or ingredient, one should describe the experimental technique and the results through which one can ascertain the molecular structure of the compound (for example, results of a magnetic resonance spectroscopy or RMN), as well as the experimental results in which sufficient evidence is provided to indicate that the compound serves to resolve the problem set out in the description. This can include comparing the efficacy of the new compound in relation to the similar compounds that are known in the state of the art and whose efficacy has been demonstrated for a given illness, *in vitro* or *in vivo* experiments or including clinical studies.

46. In the case of a pharmaceutical formulation, one should present experimental evidence that sufficiently shows that the formulation resolves a particular technical problem facing already-known formulations. For example, this includes one which achieves greater solubility, improved bioavailability, better stability, a longer lifespan, etc.

47. In the case of a therapeutic use, one should present sufficient experimental evidence to support that the use of the compound has a beneficial effect on a determined condition or illness, for example, experiments in experimental models accepted in the technical field (*in vitro*) that indicate that a compound destroys carcinogenic cells when it was only known that the same compound affected healthy endothelial cells. This evidence does not necessarily have to pass all clinical tests in order to fully demonstrate the security, efficacy and quality of the new indication for the active ingredient (while

that would be the most desirable because due to toxicity or inefficacy the medication by definition would lack industrial application). Nevertheless, in the patent application there should be sufficient evidence that demonstrates that the new indication is reasonable for the active ingredient.

48. In my firm's professional practice, we advise patent applicants (particularly for pharmaceutical patents) to include in the patent application all of the relevant history of the invention, expressly describing the differences and advantages with respect of the state of the art, as well as also including referenced and practical examples that demonstrate compliance with all of the requirements of patentability and other requirements, such as clarity and sufficiency of the description.

49. Since the 2010 reform, applicant's obligation to expressly state the purpose of the invention and exemplify practical utility can no longer be questioned. The reform grants examiners more latitude to require or request evidence of the invention's practical utility through data / findings / examples disclosed in the description in order to establish that the invention has the ability to resolve the problem originally raised in the application.

50. I do not agree with Gilda Gonzalez's assertion that examiners cannot require "*proof* of industrial applicability." Although it is true that the authorities (including IMPI) can only do what the law permits them to do, it is incorrect to suggest that they cannot require applicants to present additional or complementary information or documentation that is necessary to determine whether a patent can be granted. As a matter of fact, IMPI's power to require additional evidence is provided in Article 55 of the IPA. This provision does not limit—in any way—the type of information or documentation that can be required from the applicant.

51. While the examiner may require additional information, this does not mean that all post-filing information is considered valid by patent examiners. The information submitted must be necessarily linked to the particular feature or technique stated in the application and cannot contain additional material or claims to give a broader scope to the original application. If the feature sought to be corroborated by the information or

evidence submitted by the applicant, is not mentioned in the application, this additional information or evidence shall not be accepted by the examiner.

52. The ability to submit post-filing information does not mean that the patentability requirements may be fulfilled after the date of filing. The applicant must have an invention before filing. If the examiner believes that the information submitted with the application is insufficient to ensure compliance with the patentability requirements, the examiner may require the submission of additional information to substantiate the assertions in the application. If the post-filing information submitted shows that the applicant "completed the invention process" after the filing date, the resulting patent should be invalid.

53. The redefinition of industrial applicability in the IPA and the modification of the description requirement (in section I of Article 47) strengthened the scope and importance of the industrial applicability requirement. This—without a doubt—will be very relevant in the assessment, by Mexican tribunals, of patent invalidity cases based on lack of industrial applicability.

4. The Extent to Which Mexican Law Addresses Matters Such as Speculative Patenting / Over-Claiming

54. The IPA does not expressly address speculative patenting. Nevertheless, there are those who claim that the expression "susceptible of industrial application" in Article 16 of the IPA supports the conclusion that industrial applicability is—in itself—speculative. I disagree with this perspective because industrial applicability, as a substantive requirement, must be satisfied in the same manner as the other substantive requirements: novelty and inventive step. Additionally, I believe that this requirement should be evaluated and assessed by interpreting various provisions of the IPA and its regulations and linking it to the requirements of the description of an invention that should not be dissociated.

55. The IPA defines an invention as "any human creation that allows the transformation of material or energy existing in nature, for the benefit of mankind and the satisfaction of human concrete necessities" (Article 15). This definition clearly expresses

that an invention should be able to be exploited for mankind and satisfy concrete necessities.

56. Article 16 indicates that only "the inventions that are new, resulting from an inventive step and susceptible of industrial application" will be patentable. Article 12 of the IPA defines every one of these concepts. Section IV defines industrial application as "the possibility that an invention has a practical utility or can be produced or used in any sphere of economic activity, for the purposes described in the application." The description requirement is provided in section I of Article 47 of the IPA. This provision specifies that the description must include "the information that exemplifies the industrial applicability of the invention."

57. Section I of Article 47 of the IPA encompasses several concepts, all concerning the description of the invention. These concepts are a) the clarity and sufficiency of the description, such as the understanding of the invention and the possibility of practicing it; b) the best-known method by the applicant for practicing the invention, if it is not evident from the description; c) the information that exemplifies the industrial applicability of the invention; and d) if necessary, a record of the deposit of biological material.

58. Article 28 of the RIPA details what is established in section I of Article 47 of the IPA. The difference is essentially hierarchical, since the regulations, by constitutional mandate, cannot go beyond the Acts pursuant to which they are adopted. That is to say that the regulations are only a vehicle for carrying out the application of the Acts.

59. The requirement in Section VII of Article 28[40][42] of the RIPA[41][43]corresponds to one of the elements of the description requirement regulated in section I of Article 47

[40] Article 47 section I establishes the legal obligation of exemplifying industrial application must be respected, even when apparently Article 28 of the Regulations indicates that examples are required only when adequate. In our judicial system, regulations cannot create exceptions to the obligations established in the laws, in conformity with the principle of normative hierarchy. For this reason, while there appears to be a contradiction between articles 28 and 47, in reality, there is none. The description requirement must be fulfilled as stated in Article 47. Thus, Gilda González Carmona's arguments regarding the legal obligation to exemplify industrial application, in paragraphs 21 to 24 of her report, are exaggerated and ill-founded.

[41] Article 28.- The description shall be drafted according to the following rules: […]
VII.- It shall state the best known method, or the best method contemplated by the applicant, to carrying out the claimed invention; when appropriate, this shall be done through practical examples or specific

of the IPA. Section VII requires that the description indicate the best known method or the best way contemplated by the applicant for the performance of the claimed invention, and provide—when adequate— practical examples or specific applications of the invention. In section VIII of Article 28,[42][44] it is established that the description shall indicate, explicitly—when it is not evident from the description or the nature of the invention—the form in which the invention can be produced or used, or both.

60. Article 47 section I establishes the obligation for the applicant to exemplify the industrial application of the claimed invention. Sections VII and VIII of Article 28 of the RIPA do not preclude or limit the exemplification obligation. Nevertheless, if an applicant were to decide not to exemplify the industrial application of the claimed invention, on the basis that the regulations would *permit*—when adequate—the omission of supporting practical examples or specific applications of the invention (and the examiner tolerates this) in the description, this applicant would obtain a patent that may face invalidation. Additionally, pursuant to the principle of normative hierarchy, in the Mexican legal system the regulations cannot contain exceptions to the obligations established in Acts. For this reason, assuming there is an apparent conflict between both provisions, Article 47 section I would prevail, and as such, the obligation to exemplify the industrial application would have to be satisfied.

61. IMPI examiners do not often expressly object to a patent application for lack of industrial applicability *per se* however there have been cases where this has occurred. For example, in the first administrative decision regarding patentability requirements of patent application PA/a/2002/005224 (now patent MX 274552), the examiner objected that claims 20 to 22 and 43 to 45 had referred to methods of fertility control and concluded that these claims lacked industrial applicability based on Articles 16 and 12, section IV of the IPA. The applicant had to modify the claims in the patent application to avoid rejection. Another (recent) case is patent application MX/a/2010/004974 in which the examiner noted that "*the description section of the application lacks clarity, given*

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applications of the invention that are not of a nature that is alien to the invention described, and with references to the drawings, if any, and […]

[42] VIII.- It shall expressly state, when this is not apparent from the description or from the nature of the invention, the manner in which it may be produced or used, or both. […]

that it does not include any exemplifications of the compositions of the present invention, such as evidence that the compositions that are composed of (+) S-ibuprofen and L-arginine, present the alleged therapeutic effect that demonstrate the synergy in the proposed claims. Such exemplification would demonstrate the industrial application of the invention. Hence corrections are necessary in conformity with what is established in Article 47 section I of the reformed Paragraph DOF 18-06-2010 and Article 12 section IV reformed Section DOF 02-08-1994 and 55 Bis of the IPA in order to overcome the objections as to clarity in the description and industrial applicability of the invention."

62. Whether examiners object to patent applications because the claims in the patent applications are overly broad and speculative, or lack clarity or adequate support (such as experimental evidence), an attentive analysis of the examiners' objections shows that these objections are in fact tied to the industrial application requirement.

63. Many examples support this affirmation. Some of these include:

1) Patent MX298068[43]

In the second administrative decision regarding patentability requirements (Administrative Decision No. 42088 on June 18, 2010), the examiner indicated a) that the description was not sufficiently clear and complete in order to allow a full understanding of the invention and, where applicable, to guide its performance by a person having ordinary skills in the art; b) that the applicant did not indicate the best known method for practicing the invention and failed to included practical examples or specific applications; c) that the applicant did not explicitly indicate the form in which the invention could be produced, used or both; and d) that the sole mention and/or allegation of the possibility of obtaining a result is in no way recognized as acceptable technical and scientific experimental evidence.

2) Patent MX304904[44]

[43] Patent MX298068 "METHOD FOR TREATING MULTLPLE SCLEROSIS," property of GENENTECH, INC., granted April 11, 2012. (**R-287**)
[44] Patent MX304904 "TREATMENT OF MEDIUM AND HIGH-GRADE HODGKIN'S LYMPHOMA WITH ANTIBODY ANTI-CD20," property of BIOGEN IDEC INC., granted on November 6, 2012. (**R-286**)

In the third administrative decision regarding patentability requirements (Administrative Decision No. 31115 of May 4, 2010), the examiner indicated that the application only included a bibliographic review of scientific articles, in which the technical advantages of Rituximab were described in the treatment of medium or high-grade non-Hodgkin lymphoma (Coiffier B and col., Blood 1998), or in high grade volume non-Hodgkin lymphoma (Davis T, and col.; Blood 1998), or in patients with medium or high-grade non-Hodgkin's in combination with chemotherapy (Grossbard M, Proceedings of the American Society of Clinical Oncology 1998). Nevertheless, the application, as originally presented did not provide experimental technical examples to demonstrate the technical advantages of the claimed antibody in the treatment of high-grade no-Hodgkin lymphoma. As a result, the examiner determined that the application was speculative with respect to its alleged technical effects, and indicated that for this reason it was not clear which part of the patent application could serve as a basis for one (or several) new claim(s) that were assumedly permissible under Articles 47 section III of the IPA and 28 sections VII and VIII of the RIPA.

3) Patent MX306302[45]

In the second substantive administrative decision regarding patentability requirements (Administrative Decision No. 36444 of May 18, 2011), the examiner indicated that the description in the application did not contain elements or acceptable technical and scientific evidence through practical examples of performance, which could serve to demonstrate a) that some monoclonal antibody was had been identified; b) that this antibody has had the alleged and/or desired biological activity; c) that the antibody had been used for the formulation of pharmaceutical compositions and/or medications; and, d) that the pharmaceutical compositions and/or medications had been effective in improving the immune response of a patient.

[45] Patent MX306302 "PROTEINS AND NUCLEAC ACIDS ESCHERICHIA COLI ASSOCIATED WITH MENINGITIS/SEPSIS" property of NOVARTIS VACCINES AND DIAGNOSTICS, INC. and J. CRAIG VENTER INSTITUTE, INC., granted on December 19, 2012. (**R-285**)

5. The Criteria of Patentability With Respect to Selection Inventions and Pharmaceutical Patents with Genus Claims

64. In Mexico, the description for selection inventions must include sufficient evidence to allow for qualitative or quantitative appreciation of a new or unexpected effect relating directly to the selection of claimed compounds, taking into account the state of the art, in a way that justifies that the subject matter is patentable and also allows a full understanding of the invention and guides its performance by a person having ordinary skills in the art.

65. The examiner will have to evaluate the findings / examples / data in order to verify whether these findings permit to confirm or conclude that there exists a selection invention.

66. It should not be possible to obtain protection based on a mere allegation of a technical effect associated with a selection of compounds previously disclosed in a pharmaceutical patent with genus claims, because the application would not have fulfilled the requirements of sufficient description, inventive step, and industrial applicability.

67. In the case of a pharmaceutical patent with genus claims, it is necessary that the description contain sufficient evidence to allow a qualitative or quantitative understanding of an improved and/or desired effect that can be exclusively attributed to the group of claimed compounds, with respect to the effects already known for similar compounds in the state of the art, and in a way that justifies that the material is patentable and producible. This unexpected or improved effect can be an inhibitor effect, antagonistic effect, an agonist effect or even an effect in which the group of compounds presents fewer adverse effects, secondary effects or toxic effects, compared with the wider class of chemicals for which claims have already been made.

68. The examples, data and findings provided by the applicant should include comparative evidence of the claimed species with respect to one or several of the species that form part of the state of the art, from which it is possible to confirm the supposed improved or unexpected effect compared with those that are part of the state of the art.

69. The provided information should be sufficiently clear to allow the examiner to qualitatively or quantitatively evaluate whether the claimed compounds—that have the same use as the pharmacological family—do in fact possess the alleged advantages.

70. If it is shown that the chosen compounds present advantages compared with compounds in their family or class, the chosen compounds and their uses will be subject to patent protection.

6. Institutional Context of Mexican Patent Law, as well as its Effects on the Granting of Patents and the Related Processes of Cancellation in the Mexican System

71. IMPI was established in 1994.[46] Prior to its creation, the General Direction of Technological Development was the authority in charge of industrial property matters.

72. IMPI issues annual reports on its activities. The first report that it issued since the date of its creation was its 1994-1996 Annual Report. The level of detail in the annual reports does not allow for a precise record of how many patents applications there were or how many were granted in the pharmaceutical field or how many examiners worked in the different areas of substantive examination throughout IMPI's history. It also does not precisely indicate the level of education for every examiner in every area.

73. What is evident is that since its creation, IMPI has been gradually increasing the total number of examiners and their education level.[47] The number of patent applications has also increased from year to year. Between 1993 and 2013, the average number of patent applications in all technical areas, has been 12,500 per year on average, and the number of patents granted per year is on average 7,000.[48]

74. There is no database that identifies patent applications specific to the pharmaceutical field. Additionally, there was no independent pharmaceutical patent

[46] Decree that mandates the creation of IMPI, Official Diary of the Federation of December 10, 1993 [Decree of December 10, 1993] (**R-288**).
[47] This is evidenced by the Administrative document SDRH.2014.2320 of the Divisional Human Resources Branch IMPI , issued on December 10, 2014. (**R-289**)
[48] IMPI in numbers 2014 (1993 – September 2014). Accessed on January 25, 2015. See online: <www.impi.gob.mx/QuienesSomos/ICIFRAS/IMPI%20en%20CIFRAS%20ene%20sep%202014.pdf> [IMPI in numbers] (**R-290**).

section in IMPI prior to 2007.[49] Before 2007, the General Chemical and Biotechnological Section dealt with the evaluation of pharmaceutical patent applications. When Claimant's olanzapine and atomoxetine patent applications were evaluated the pharmaceutical patent section had yet to be created.

75. The IMPI Annual Reports indicate that since 1994 there has been a backlog of pending applications and material and human resources were continually augmented to address the delays and to improve the quality of patent application evaluations.

76. IMPI's workload and the limited number of patent examiners have resulted in expedited patent application examinations. When dealing with a patent application previously granted by a foreign patent office, Mexican patent examiners suspend their ongoing analysis and only require that the applicant adjust the claims of the Mexican patent application to match those of the granted foreign patent application.

77. This practice favors the granting of patents that, but for an expedited examination might have been denied under strict application of Mexican law (for not fulfilling the legal requirements) or granted in a more limited form. Given that the majority of patents filed in Mexico belong to foreigners, it is foreseeable that many patents granted in Mexico, including those at issue in this proceeding, underwent an expedited examination.[50]

78. IMPI, therefore, frequently does not complete a substantive examination and grants multiple patents prematurely upon simple presentation of an equivalent patent granted in another jurisdiction. Additionally, competitors of the transnational pharmaceutical companies in Mexico generally do not have the financial capacity to pursue the large and complex litigation necessary to challenge patents that ought not to have been granted. This is in addition to the fact that Mexico does not have an efficient process in place that would prevent the granting of patents that do not adequately meet patentability requirements.

[49] Decree that reforms and adds the Regulation of IMPI, Official Diary of the Federation of September 7, 2007 [Decree of September 7, 2007] (**R-291**).
[50] See IMPI in numbers. (**R-290**)

79. Mexican tribunals' knowledge regarding patent law in general is developping—moreover pharmaceutical patents tend to be complex, and judges and lawyers usually lack the requisite technical knowledge. The lack of certainty about the viability of canceling a patent, the duration and the high costs associated with this type of litigation deter challenges to patent validity. Additionally, in Mexico the possibility to claim costs from the losing party (in the administrative sphere) does not exist. As a result, the parties have to assume their own costs. At least in the pharmaceutical industry, the financial capacity of Mexican businesses tends to put them at a disadvantage with respect to the owners of foreign patents as the cost and duration of litigation tends to be a determinative factor in deciding whether to challenge a patent that may be invalid.

80. Concepts like industrial applicability, novelty and inventive step are undetermined legal terms whose contents need to be shaped through practical application by the patent authority (IMPI) and, subsequently, through judicial interpretation.

81. I am not aware of any case in which Mexican tribunals had to interpret the concept of industrial applicability. Nevertheless, were the occasion to arise for a tribunal to interpret this concept, in my opinion the Mexican tribunals would have to make an interpretation consistent and harmonious with the IPA and the Congressional Declaration of Purpose of the 2010 reform.

82. In my professional practice I have participated in litigation that has culminated in the nullification of pharmaceutical patents, either for not having fulfilled the various formal requirements,[51] or because the patent had been granted although it failed to fulfill the requirements of novelty and/or inventive step and/or for insufficient description or lack of clarity[52]. As I have noted, in Mexico, "descriptive insufficiency" is often equivalent to lack of industrial applicability.

[51] Formal requirements refer to all documents related to the patent application including for example, power of attorney, priority document, etc.
[52] Patent 181200 (for formal deficiencies); Patent 178535 (lack of novelty and inventive step); Patent 234559 (lack of inventive step).

83. In the pharmaceutical field, one frequently encounters patents that should not have been granted but that remain valid so long as they are not challenged by a third party with a legal interest.[53]

84. However, the path to invalidate a patent in Mexico is long, costly and complicated. Anyone challenging a patent will face various obstacles. The first obstacle that the challenging party faces is establishing a legal interest to challenge the validity of a patent. This concept demands, in general terms, that the challenging party own a right in conflict with the challenged right (in this case the patent); or that it wait to be sued in an infringement proceeding regarding the patent, to challenge the nullity of the patent based on the infringement action. In the case of pharmaceutical patents, these two scenarios complicate the situation to such a degree that with each new case it becomes more difficult to challenge the validity of patents granted in contravention of the requirements of the law.

85. The process for challenging the validity of patents in Mexico is long and complicated. It begins with an application to IMPI for an administrative declaration of nullity. The duration of the proceeding depends on the complexity of the patent and the type of proof offered[54] and it may last between a year and a half and three years to be resolved.

86. Once the IMPI proceeding is concluded, the decision may be reviewed two more times.[55] First comes a Nullity Suit before the Federal Tribunal of Fiscal and Administrative Justice through the Specialized Intellectual Property Chamber ("SEPI").[56] This proceeding lasts between a year and a half to two and a half years. The decision of

[53] Mexican law provides that the authority's acts, as is the case of a patent granted by IMPI, are valid has long as they are not revoked in the corresponding jurisdictional instances (Article 8 of the Federal Law of Administrative Procedure).
[54] If expert evidence is submitted the proceeding tends to take more time to be resolved.
[55] Mexican law provides that the authority's actions, as is the case of a patent granted by IMPI, are valid has long as they are not revoked in the corresponding jurisdictional instances (Article 8 of the Federal Law of Administrative Procedure).
[56] If expert evidence is submitted the proceeding tend to take more time to be resolved.

the SEPI may then be reviewed in a Direct Amparo proceeding[57] before a Collegiate Circuit Tribunal in Administrative Law. The total length of ensuing patent litigation may take from 3 to 7 years. As a result of these various impediments, very few patent cases are litigated before Mexican courts.

87. A damage claim may only be presented once the prior administrative options have been exhausted and the declaration (and, in its case, refusal of the nullity of the patent) has become final. In principle, the competitor that also has been sued for infringement of a patent can demand redress for loss and damages when the decision denying the infringement or upholding the invalidity of the patent, is final. This claim for damages is sought before a civil judge. Civil litigation is very long (approximately seven years) with many possibilities for intermediate appeals and subsequent actions.

88. Given these impediments, I am not aware of proceedings for damages and losses based on the infringement of pharmaceutical patents.

7. The Validity of the Claimant's Patents (Equivalent to the Canadian Patents at Issue in this Proceeding) Under Mexican Law

89. Patent MX173791 (olanzapine, a selection invention, whose term expired in Mexico on April 24, 2011) and patent MX202275, (atomoxetine) have not been challenged in Mexico.[58] I disagree with the Claimant that this leads to the conclusion that the two patents were validly granted. Also, I do not agree with the opinion of Chemist Fabián Salazar regarding the alleged validity of these two patents.

[57] Amparo Directo, is one of the mechanisms built into the Mexican legal system to safeguard the supremacy of the Constitution over conflicting laws and governmental acts. This type of procedure available for enforcement of the Mexican Constitution is not part of the ordinary judicial process. It encompasses all processes that must be heard in a single stage before panels of circuit court judges. It is the process designed for individuals to assert their right to judicial protection against a judgment of any Mexican court at any level of government, local, state, or federal, in either criminal, civil administrative, or labor matters.

[58] To verify this, I made two requests to IMPI. As stated in the documents DDPPI.2014.638 (Patent MX202275) (**R-293**) and DDPPI.2014.640 (Patent MX173791) (**R-294**), the Divisional Directorate for the Protection of Intellectual Property of IMPI confirmed that there are no proceedings for revocation (requests for administrative declaration of invalidity) of these patents.

90. Patent MX202275 (atomoxetine) was granted in Swiss-type, unlike its equivalent CA2209735, which was obtained directly for its use in the treatment of attention deficit disorder / hyperactivity.[59]

91. Despite this discrepancy, the claimed material in the Canadian patent and its equivalent in Mexico are not substantially different.

92. Patent MX173791 (olanzapine) presents differences with respect to the equivalent CA2041113, though these differences are not really substantial.

93. Both patents coincide in protecting 1) a process for producing olanzapine (claim 1 in the Mexican patent and claim 20 in the Canadian patent); 2) the olanzapine itself (claims 3, 5 and 6 in Mexican patent and 1 through 3 in the Canadian patent); 3) the use of the olanzapine (claim 7 in the Mexican patent and 5 through 9 in the Canadian patent); and 4) the pharmaceutical composition (claims 4, 8, 9 and 10 in the Mexican patent and 10, 13 through 19 in the Canadian patent).

94. The most apparent differences are that in the Canadian patent a different compound than olanzapine (Intermediary) is additionally protected in claim 21, whereas in Mexico it is not; 2) in Mexico the process of preparing the pharmaceutical composition is protected, but in Canada it is not; and 3) in the Mexican patent the uses that were claimed in the Canadian patent were not claimed (schizophrenia, acute mania, and states of anxiety).

95. I reviewed the electronic docket of patent MX202275 (atomoxetine) in IMPI's Industrial Property Document Viewer, and Mauricio Caballero[60] helped me with the present analysis.

[59] Claim 1 of patent CA22097351 covers the "use of atomoxetine for the treatment of attention deficit disorder / hyperactivity in a patient with the need for the same; and claim 1 of equivalent patent 202275 in Mexico covers the "use of atomoxetine for preparing a pharmaceutical composition for treating a sickness of hyperactivity-deficit of attention."

[60] Mauricio Caballero Galván worked at IMPI from May, 2000 to August, 2011, the Department of the Coordination of Background Examinations, Biotechnology Area and from 2006 as Supervisor of the Pharmaceutical Area. He returned to work at A&L in September, 2011. (**R-295**)

96. Patent MX 202275 was filed in Mexico on July 8, 1997 as the national phase of international patent application No. PCT/US1996/000091, claiming as priority the North American application of January 11, 1995, No. 08/371,341, which was assigned application number PA/a/1997/005117.

97. IMPI issued only one substantive office action in which it required elimination of claims 1 through 16 for referring to therapeutic treatment methods and it asked that the applicant present the category "Y" documents cited in the Search Report for International application No. PCT/US96/00091. In response, the applicant presented these documents and arguments related to the inventive step of the claimed chapter. Afterwards, on June 12, 2001, IMPI granted patent MX 202275.

98. Nevertheless, after having analyzed Mexican patent MX 202275, we found that the description did not, at all, contain experimental information that technically and scientifically supports the assertion that atomoxetine is effective in the treatment of ADHD in children, adolescents and adults.

99. Thus, in light of the complete absence of information, the examiner should have required that the applicant present information or documentation that would reasonably support the claims, together with information on the state of the art, that prior to the priority date the alleged effects had been effectively proven, namely that there existed scientific bases for affirming that atomoxetine was effective in the treatment of ADHD.

100. In the event the applicant did not present the required information the result should have been the refusal to grant the patent for non-completion of the requirements of Inventive Step, Industrial Applicability and Sufficiency of the Description.

101. I reviewed the electronic docket of patent MX 173791 (ZYPREXA) in IMPI's Industrial Property Document Viewer, and Juan Luis Espinosa Pérez[61] helped me with the present analysis.

[61] Juan Luis Espinosa Pérez worked at IMPI from December, 2006 to February, 2013. He was an "A" Specialist in Industrial Property assigned to the Subdirection of Background Examination of Patents,

102. We found that patent MX173791 was presented in Mexico on April 24, 1991, under the Law of Inventions and Trademarks, claiming as priority the application of English patent GB90092297 of April 25, 1990. The Mexican patent was assigned application No. 025502.

103. After completing the formal requirements, the applicant pushed for the conversion of his patent application under the transition provisions of the former PPIPA, requesting that it be registered under the new Act that would allow the protection of pharmaceuticals.

104. The applicant presented new claims related to the compound 2-metil-10(4-metil 1-piperazinil)-4H-tieno [2,3-b] [1,5] benzodiazepine, or a similar acidic salt, and claims for the pharmaceutical composition, capsule, tablet and injectable formulation that comprise this compound, and kept the process claims that were originally presented.

105. The applicant indicated that its invention was related to Central Nervous System disorders, in particular with the treatment of schizophrenia from a chemical compound (olanzapina) and claimed the compound 2-metil-10(4-metil 1-piperazinil)-4H-tieno [2,3-b] [1,5] benzodiacepine (olanzapine), its process of production and a pharmaceutical compound.

106. A diligent examiner should have questioned the validity of this study that only considered 8 subjects, with the knowledge that with such a small group of subjects, and rapid evaluations of the changes produced in the symptoms of mental patients (the Brief Scale of Psychiatric Evaluation (BSPE)), one cannot arrive at a conclusive result, much less in the area of therapeutic treatments.

107. Given that this was a selection invention, the examiner also should have sought information demonstrating that the claimed compound (olanzapine) had fewer toxic effects in relation to the compounds of similar chemical structures, such as flumezapine or clorpromazine; as well as information from the favorable profiles of functional activity

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Biotechnological, Pharmaceutical and Chemical Areas. He was employed at Arochi & Lindner in February, 2013. (**R-296**)

in in vitro tests. The patent only mentions the value of the IC50 for linking tests of 3H-SCH23390 and 3H-spiperona, values with which it is possible to measure the degree of connection with or union of olanzapine with the neural receptors. However, these tests do not make it possible to determine olanzapine's functional activity (agonist or antagonist), nor still less do they conclusively attribute an antipsychotic effect to olanzapine.

108. In the absence of all of this information, the examiner should have objected to the patent due to lack of Inventive Step (the applicant did not show advantages of olanzapine in comparison with similar compounds in the state of the art such as flumezapine or clorpromazine), lack of Industrial Applicability (the applicant did not show experimental examples of the use of olanzapine for treating any specific neurological condition since it was only left to speculate that olanzapine could be useful in neurological conditions in general) and Insufficiency in the Description (the applicant did not show experimental examples that support the conclusion that olanzapine was useful in the treatment of at least a neurological condition).

109. This patent was granted in March of 1994, when IMPI had recently been created. As I have noted, at that time, the patents that were granted were frequently evaluated with less technical rigor and with deficiencies in evaluating the criteria of patentability.[62]

Signed at: New York City, U.S.A. on: January 26, 2015

[signed]

Hedwig Lindner

[62] A reference to the level of human and material resources that IMPI had during that period can be found in the annual report 1994-1996: "At the beginning of 1996, the Institute still did not have an adequate organic-functional structure that allowed it to complete its objectives and measures and to resolve the needed operations for the respective areas to which they belonged; further, the available informational resources at the beginning of the year were still insufficient to give timely responses to users." (Human Resources Section) Accessed on January 25, 2015. See online: <www.impi.gob.mx/QuienesSomos/Documentos%20Varios/IA1994.pdf>.

HEDWIG A. LINDNER LÓPEZ

August 12, 1964
Insurgentes Sur 1605 Piso 20, colonia San José Insurgentes, delegación Benito Juárez, Mexico City
(01 52 55) 50 95 20 50
hlindner@aml.com.mx
hlindner@arochilindner.com

Education

- Bachelor of Laws (LL.L.) -- *Universidad Panamericana* (1989)

- Post-graduate degree in extraordinary constitutional procedures (Amparo proceedings) -- *Institute of Judicial Specialization of the Supreme Court of the Nation* (1990)

- Master of Laws (LL.M.) in Constitutional and Admistrative law -- *Universidad Nacional Autónoma de México* (1991-1993)

- Master of Laws (LL.M.) in International Intellectual Property Law -- *George Washington University* (1993-1994)

- Ph.D. Candidate -- *Universidad Panamericana* (2007-2008)

Work Experience

- Hedwig (Heidi) Lindner López is a founding partner of Arochi & Lindner.

- She has 30 years of experience in the practice area of Intellectual Property Law, nine of which she spent as an associate and partner of an international law firm.

- Her specialization is litigation and, in particular, matters relating to Intellectual Property Law and Life & Sciences Law.

- She has been a Legal Adviser to the National Association of Medecine Manufacturers since 1999.

- She has been a Lecturer in the Master of Laws program at the Universidad Panamericana since 2004.

Professional recognition

- Listed in *Chambers Latin America* since 2008 as one of the best lawyers in intellectual property in Mexico.

- In 2008 she was awarded the honor of Highly Recognized Attorney in the category of patent litigation in the global *World Leaders Award*.

- In 2004 Heidi Lindner was nominated as one of the world's leading litigation attorneys in intellectual property by *Who's Who Legal*.

- Listed by *Global Counsel 3000* since 2001 as one of the world's leading attorneys in intellectual property.

- Appears in the 2015 edition of *Chambers Latin America* as one of the leading attornies in Mexico in intellectual property.

Associations

- Ms. Lindner was President of the Mexican Association for the Protection of Intellectual Property from 1998 to 2001. In addition, she belongs to the following associations: Mexican Bar Association, International Trademark Association, Inter-American Association of Intellectual Property, International Association for the Protection of Intellectual Property and American Intellectual Property Lawyers Association.

Publications

The Impact of Public Health Issues on Exclusive Patents Rigths (Anuario de la Asociación Internacional para la Protección de la Propiedad Intelectual, 2008).

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