

**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)

SECOND EXPERT REPORT OF HEDWIG A. LINDNER LÓPEZ

December 7, 2015

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I. Introduction

1. For the purposes of this second report, the Government of Canada has requested that I review and consider the opinions expressed in the Second Expert Report of Fabian Ramon Salazar, dated September 10, 2015, and the Second Expert Report of Gilda González Carmona, dated September 10, 2015 in support of Claimant's Reply.
2. This report responds to observations and arguments made by Mr. Salazar and Ms. González in their Second Expert Report. The fact that not all comments were addressed does not imply that I concede these points or that I agree with the Claimant's experts. I reserve my right to respond to other arguments in due course and I reiterate all the opinions of my first report, notably with respect to the questionable validity of Claimant's patents for olanzapine (MX173791) and atomoxetine (MX202275).
3. Arguments made in my first report will not be repeated here, but will be referred to, so as to provide further explanation to some of my remarks in the current report.
4. Ms. González argues in her Second Report that the industrial applicability requirement was established in the Mexican *Promotion and Protection of Industrial Property Act* in 1991 for the implementation of NAFTA and that it was not modified by the 2010 amendments. This argument ignores the clear legislative history. Further, her recollection of patent validity challenges before the Mexican Institute for Industrial Property (IMPI) is also inaccurate, as the numbers she puts forward are diametrically different from the information provided by IMPI.
5. Mr. Salazar argues in his Second Report that he did not witness any changes in IMPI's practice regarding the industrial applicability requirement following the 2010 legal reform, and that in any event, the legislative modifications did not require any changes to IMPI's practice. To make such assertions, Mr. Salazar must disregard the legislative intent clearly expressed in several parliamentary documents. Additionally, it would be unreasonable to expect changes in the law to be reflected in the practice immediately upon publication of the amendments in the Official Gazette, I nevertheless identified

examples in my First Report that show a clear variation in the approach taken to examine patent applications after 2010.

6. In response to the arguments raised by Ms. González and Mr. Salazar, this Second Report makes the following points:

- (I) The industrial applicability requirement is based on the Mexican 1976 *Inventions and Trademarks Act*, and not on NAFTA negotiations.
- (II) The 2010 Amendments modified the industrial applicability Requirement.
- (III) The 2010 Amendments required that evidence of industrial applicability be included in the Application.
- (IV) The 2010 Amendments altered IMPI'S practice regarding the requirement of industrial applicability.
- (V) The patents cited and analyzed in my First Expert Reports are valid examples of patent applications that lacked industrial applicability.
- (VI) Had the Claimant's patents be challenged under the industrial applicability requirement, they would have been invalidated.

II. The Requirement of Industrial Applicability in Mexico was not influenced by NAFTA

7. In her Reply to my first report, Ms. González argues that the industrial applicability requirement in Mexico was based on international standards set out in NAFTA.¹ This is incorrect. The requirement of industrial applicability first entered Mexican patent law with the enactment of the *Inventions and Trademarks Act* in 1976. Article 4 of the *Inventions and Trademarks Act* stated that to be patentable, “an invention must be novel, the result of an inventive process, and be capable of industrial applicability”. Article 8 stated that an invention is deemed “capable of industrial application if it can be manufactured or used by the industry”. The 1976 Act also strictly limited the types of inventions that were patentable – expressly excluding pharmaceutical products and drugs (Article 10).

8. In 1991, Congress repealed the 1976 Act and replaced it with the *Promotion and Protection of Industrial Property Act*. The 1991 Act expanded the range of patentable

¹ Reference to González Second Report, paras. 3, 5, 10.

subject matter, and allowed the patenting of pharmaceutical inventions for the first time. However, the standard of industrial applicability itself (found in Article 12.IV of the 1991 Act) was substantively the same as under the 1976 Act.²

9. NAFTA came into effect in 1994. I note that Article 1709(1) of NAFTA states that “each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application.” However, the treaty does not specify how “capable of industrial application” should be understood or implemented.
10. As part of Mexico’s implementation of NAFTA, the 1991 Act was amended and became the *Industrial Property Act* (IPA). The 1994 amendments were mainly procedural.³ Although some changes were made to Article 12.IV, the threshold of industrial applicability remained essentially unchanged.⁴
11. In short, the original industrial applicability requirement in Mexican patent law predated NAFTA and TRIPS by many years and was not amended substantively during the implementation of Mexico’s obligations under either agreement. In fact, the first substantive change to the industrial applicability requirement in Mexico occurred 34 years after the concept was initially introduced in Mexican patent law, when Congress amended the IPA in 2010.

² Article 12.IV of the 1991 Act states that industrial applicability must be understood as “the possibility that any product or process **be produced or used**, as the case may be, in **the industry**, which shall include agriculture, ranching, fishing, mining, the processing industries per se, the construction industry and all types of service industries.”

³ Lindner First Report, para. 25.

⁴ Ms. González agrees that the 1994 amendments made some changes to the definition of “industrial applicability” in Article 12.IV of the IPA, but did not alter the substance of the standard (González Second Report, paras. 13-14). Ms. González points out that, in my first report, I accept that no substantive change was needed in 1994 (González Second Report, para. 14). This is correct and precisely confirms that this change was unnecessary because the NAFTA did not provide a definition of the patentability requirements (including that of industrial applicability) that required any particular implementation.

III. The 2010 Amendments Substantively modified the Industrial Applicability Requirement in Mexico

12. As discussed in my First Report, the 2010 amendments modified both substantive⁵ and procedural⁶ provisions of the IPA. Importantly, some of the substantive amendments show that the way that the industrial applicability requirement was being understood and applied in Mexico at the time did not correspond to Congress' views on industrial property.⁷

13. Since the 2010 amendments, Article 12.IV provides the following (I have highlighted the changes in bold):

For the purposes of this Title, will be considered:

IV. Industrial applicability, 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.** (...)

14. The purpose of the changes to the industrial applicability requirement was discussed in the Congressional Declaration of Purpose and the Congressional Study.⁸ The Congressional Study of the Senate expressly states that the terms “for the purposes described in the application” was added to Article 12.IV, precisely to “limit the practice of filing patent applications that have not completed the development of the industrial applicability in order to guarantee a filing date, without having specified the utility of the invention.”⁹ Thus, the 2010 modifications aimed at making sure the industrial applicability requirement would be applied in a manner consistent with the patent bargain.¹⁰

⁵ Lindner First Report, paras. 34-38, i.e. Articles 12.IV; 41; 47.I; and 59.VI.

⁶ Lindner First Report, paras. 39-40, i.e. Articles 6.X; 52 Bis; 188; 199 Bis 1; and 213.XXVII.

⁷ Congressional Study of the United Comissions of Commerce and Industrial Development, of Health and Legislative Studies Second (“*Congressional Study – Senate- 2010 Reform*”), Senate’s Gazette of December, 2009 p. 6 (**R-276**).

⁸ See Lindner First Report, p.8, FN 13-14.

⁹ *Congressional Study of the Senate – 2010 Reform*, p. 6 (**R-276**).

¹⁰ Congressional Study of the Senate – 2010 Reform, p. 1 (**R-276**) (“to ensure a better balance between promoting creativity and innovation that grants patent right holders with exclusive rights to the invention and the public interest and social benefit”).

15. In their Second Reports, Ms. González and Mr. Salazar acknowledge the 2010 amendments to Article 12 (IV). However, they both dismiss the changes¹¹ as only introducing “better wording” to clarify that the Mexican requirement is similar to the concept of utility,¹² and as restating what already exists in other provisions. On this basis, they both argue that the legal standard remained the same and the practice did not change.¹³
16. Ms. González and Mr. Salazar’s interpretation of the amendments to Article 12 (IV) is erroneous for at least three reasons. First, nowhere in the legislative history surrounding the adoption of the modifications to Article 12 is there mention that “practical utility” is a term of art, or that it sought to clarify the similarity between the concept of industrial applicability and that of utility.
17. Second, the legislative debates mention that “practical utility” refers to the invention’s capacity to solve a specific issue or address a particular situation and thus, its introduction to the Article would ensure that utility is foreseen in the patent application.¹⁴
18. Third, one cannot accurately state that the 2010 amendments did not modify the way industrial applicability ought to be established.¹⁵ As a matter of fact, the modifications of Articles 12 and 47 IPA clarify the application of Article 28 IPAR.

Article 47 - A patent application shall be accompanied by:

¹¹ Ms. González based her conclusion on “personal experience” and a “consensus among [her] colleagues” (González Second Report, para. 21). She does not specify to which colleagues she refers, which makes it impossible to verify the accuracy of such assessment. As for her personal experience, Ms. González was not involved in substantive patent matters at IMPI when the amendments were enacted. From 2009 to 2011, Ms. González was in charge of the Support Services Subdivision at IMPI. According to IMPI’s internal regulations, and the administrative agreement establishing the duties of IMPI’s Public servants, the Support Services Subdivision is not responsible for substantive matters relating to patent prosecution or litigation, which are the responsibility of the Industrial Property Subdivision.

¹² González Second Report, para. 24.

¹³ For instance, Ms. González argues that the additional requirement relating to written description (“for the purposes described in the application”), already existed under Article 28.VIII of the Industrial Property Act Regulations (IPAR), which, according to her, does not require that industrial applicability be expressly stated in the application when it is evident from the description or nature of the invention.

¹⁴ The “concrete” component imbedded in the “capable of industrial applicability” requirement is also found under Article 15 of the IPA: “will be considered an invention [...] what can satisfy men’s concrete needs”.

¹⁵ Salazar Second Report, paras. 20-22; González Second Report, paras. 21-26.

I. The description of the invention, which must be sufficiently clear and complete to enable a full understanding of it and, where appropriate, to guide its accomplishment for a person who possesses know-how and average knowledge in the matter. Likewise, when it is not clear from the description of the invention, it must also include the best method known to the applicant to implement the invention, as well as information that illustrates the industrial application of the invention...

19. As can be seen above, since the 2010 amendments, Article 47(I) requires that all patent applications include information exemplifying the industrial applicability of the invention,¹⁶ otherwise the application risks being denied or the patent risks invalidation.¹⁷

20. For these reasons I also disagree with Mr. Salazar's assertion that the requirement of sufficient disclosure is unrelated to the requirement of industrial applicability because these requirements appear in different articles of the IPA.¹⁸

21. Ms. González and Mr. Salazar's reports also neglect to mention important portions of the Congressional Declaration of Purpose and the Congressional Study of the Senate which supported the 2010 amendments. It is clear from these documents that the 2010 amendments made substantive changes to the industrial applicability requirement.¹⁹

22. In sum, Ms. González and Mr. Salazar are wrong when they assert that the 2010 changes did not alter the legal requirements for obtaining a patent²⁰ or impose a more demanding disclosure standard regarding industrial applicability.²¹

- The 2010 amendments added the following terms to Articles 12.IV and 47.I:

¹⁶ If Article 12.IV of the IPA and Article 28 of the IPAR were to be considered inconsistent, the IPA would prevail, because in Mexico, as in most other countries, statutes are superior in the hierarchy of laws to regulations.

¹⁷ See Article 78 of the IPA.

¹⁸ Salazar Second Report, para. 28.

¹⁹ Annex I show the relevant sections that were omitted in Ms. Gonzalez' analysis.

²⁰ Ms. González repeatedly insists that a patent applicant need not prove that the invention is industrially applicable. In support of her erroneous position, she cites what she claims to be the text of Article 47.I. However, the text quoted in her Second Report is not the text enacted by Congress. Mr. Salazar affirms that the IPA and its regulations do not require evidence for establishing industrial applicability. He insists that the clarity of the description is enough for complying with the industrial applicability requirement (which confirms that the "clarity" requirement also applies to the disclosure of the industrial applicability for the purposes described in the patent application).

²¹ González Second Report, para. 37; Salazar Second Report, para. 23. Mr. Salazar does not share the assertion I made in my First Report with respect to the fact that Article 55 of the IPA does not limit in any way the type of information or documentation that can be required from the applicant. Mr. Salazar's view contradicts the text of Article 55 of the IPA.

- “has a practical utility” (Article 12.IV)
 - “for the purposes described in the application” (Article 12.IV)
 - “as well as the information exemplifying the industrial applicability of the invention” (Article 47.I).
- Both the Congressional Declaration of Purpose and the Congressional Study of the Senate noted the problem of premature patent applications; that is, applications filed before the industrial applicability of the invention was fully understood. The amendments to Articles 12.IV and 47.I attempted to address this problem, by requiring applicants to describe and exemplify the industrial applicability of the claimed invention.
 - The procedural requirements of Article 47.I, patentability requirements, and the substantive requirements of Article 12.IV cannot be understood in isolation from one another.

IV. The 2010 Amendments make it clear that Evidence of Industrial Applicability must be included in the Application

23. In my first report, I pointed out that an applicant for a pharmaceutical patent must, like any other patent applicant, demonstrate the industrial applicability of the invention. I agree with Mr. Salazar when he says, in his Second Expert Report, that the level of detail needed to meet the patentability requirements depends on the circumstances of the case, including the state of the art and technical problem that the claimed invention solves.²²
24. However, I disagree with Mr. Salazar’s assertion that it is unnecessary to provide evidence demonstrating the industrial applicability of an invention in Mexico.²³ According to Mr. Salazar, Article 47.I states that a patent application must contain information supporting the industrial applicability of the invention *only* if it is not clear from the description. Mr. Salazar misreads the text on which his statement is based. The portion of Article 47.I on which Mr. Salazar relies concerns the best mode of practicing the invention, and not its industrial applicability. While it is true that an applicant only needs to provide information on best mode if it is not obvious from the description, the statute makes no such distinction in the case of industrial applicability. The text clearly states

²² See Salazar Second Report, para. 27 *in fine*.

²³ Salazar Second Report, paras. 24-28.

that the applicant must provide information relating the industrial applicability of the invention in *all* cases.

25. This is especially important in the context of pharmaceutical products. With such products it is often practically impossible to support the industrial applicability of an invention without scientific evidence. Pharmaceutical patents cover compounds, formulations or compositions that are used to treat or prevent diseases or conditions by interacting with biologically complex organisms in often unpredictable ways. As a result, showing that a pharmaceutical patent application has satisfied the standard of industrial applicability is more complex than showing that a patent application for a mechanical invention has satisfied this standard.²⁴
26. Further, many patent applications in the pharmaceutical field involve “inventions of selection” or new uses of previously-existing substances. Because these applications necessarily refer to previously described matter that in most cases has already been disclosed, the burden of demonstrating the industrial applicability in the pharmaceutical field is usually higher.
27. As a result, applicants for patents in the pharmaceutical field frequently allege that an invention produces “surprising effects,” “synergies” or “improved therapeutic effects” – in other words, improved performance in comparison with known compounds. The very nature of these claims requires them to be supported by scientific evidence; without such evidence, IMPI would be granting patents on the basis of mere speculation.²⁵
28. Where the industrial applicability of an invention resides in its ability to cure, or treat or prevent a disease or condition through the therapy with a substance, thus resolving a health problem – it is necessary in Mexico to support the assertion of industrial applicability in a patent application. It is for this reason that, as stated in my original report, in my practice, I advise clients to establish Mexico’s industrial applicability

²⁴ The mechanical invention either works or does not work.

²⁵ In the case of selection patents, the applicant may allege an unexpected effect, such as an increase in bioavailability or a specific therapeutically beneficial synergy. It is inconceivable that such a patent would be granted without credible scientific evidence that the claimed effect is real. Without such evidence, the patent should either be refused or declared invalid.

requirement by submitting evidence, in the form of *in vitro* studies, animal studies or the like (i.e. to establish that the applicant is effectively in possession of the invention as of the filing date).²⁶

V. The 2010 Legal Reform Altered IMPI's Practice

29. Contrary to what Ms. González and Mr. Salazar insinuate,²⁷ the 2010 amendments to the IPA have resulted in changes to IMPI's practice with respect to the application of the industrial applicability requirement, at least in the area of pharmaceutical patents.²⁸ Mr. Salazar's more specific contentions are addressed below.

30. The description of the invention is the part of the application that brings together the substantive requirements for patent protection, including the requirements of novelty, inventive step and industrial applicability. As a result, the description is the part of the application where the applicant either demonstrates or fails to demonstrate its right to the patent.

31. The Mexican law requires that the description be clear, complete and adequately supported. With respect to the industrial applicability requirement, the 2010 amendments made it clear that this is an independent patentability requirement, and as such it must be explicitly addressed in the application and duly supported so that the examiner can determine whether the application establishes compliance with all legal requirements.²⁹ Mr. Salazar recognizes that an applicant cannot overcome a lack of sufficiency in

²⁶ Lindner First Report, paras. 44-48.

²⁷ Salazar Second Report, section IV A-B; González Second Report, section IV A-C.

²⁸ As I mentioned in my First Report (paras. 48-53), this evolution in practice is an unavoidable consequence of the diversification of patented subject matter, arising mainly from new chemical entities patented on the basis of very early preclinical stage research, formulation patents, patents of new synthesis routes, patents of new salt or crystal forms based on late preclinical research stages, and patents on new medical uses based on findings during clinical assays. These types of patents have proliferated in most parts of the world, requiring local patent offices to develop criteria for new types of patentable subject matter.

²⁹ Congressional Declaration of Purpose – Senate – 2010, pp. 4 and 5 (**R-283**); *Congressional Study – Senate – 2010*, p. 6 (**R-276**)

disclosure by adding new examples or fulfilling the substantive requirements, because this would violate Articles 55 and 55 *bis* of the IPA.³⁰

32. In his First Report, Mr. Salazar affirmed that he did not remember any case where an examiner requested additional information to satisfy the requirement of susceptibility of industrial application.³¹ In my first report I cited some examples of applications that faced objections under Article 47.I due to an insufficient or unclear description.³² Although such objections are typically phrased in procedural terms (insufficiency of the description), they are in effect substantive objections due to a lack of industrial applicability.

33. IMPI's practice with respect to the industrial applicability requirement has been evolving since before Mr. Salazar left the agency in 2012, and has continued to evolve. Of course, it takes time for any statutory amendment to be fully understood and implemented due to institutional and human issues, particularly when implementation of an amendment creates more work for examiners.³³ It is unrealistic to expect change in the law to be reflected in practice immediately upon publication of the amendment in the Official Gazette.

³⁰ Salazar Second Report, p.12, FN 40. Article 55 of the IPA clearly states that IMPI may require in writing that the applicant present additional information or documents, modify the claims, description or drawings, or make necessary clarifications, when (i) such information, documents or amendments are deemed necessary by IMPI so that substantive examination can proceed; or (ii) when during or as a result of substantive examination IMPI discovers that the invention does not meet the requirements for patentability, or falls within one of the bases for refusal contained in Articles 16 or 19 of the IPA. Additionally, Article 55 bis states that required submissions of documents or voluntary amendments may not contain additional subject matter or claims that expand the scope of the original claims when considered as a whole.

³¹ Salazar First Report, para. 26.

³² Reference to Lindner First Report, paras. 61-63.

³³ Lindner First Report, para. 63: Two of the official actions I pointed out in this report were issued before the effective date of the 2010 amendment. In addition, the three official actions belong to the time in which Salazar was the Divisional Director of Patents of IMPI. These official actions show that evidence of industrial applicability was being requested by examiners even before the amendments. So in this sense, the amendments reinforced an evolution of IMPI's practice that was already taking place.

VI. As Shown by Patent Cases MX298068, MX304904, and MX306302, Industrial Applicability is a Serious Barrier to Patent Issuance³⁴

34. In my first report I cited Patents MX298068, MX304904, and MX306302 as examples of patent applications where applicants faced objections due to their failure to establish the industrial applicability of the invention. In his Second Report, Mr. Salazar argues that industrial applicability is not a serious barrier to patent issuance, because in all of the cases I cited, the patents were eventually granted.³⁵

35. While it is true that the cited Patents were eventually granted, they all underwent prior significant amendments. For instance, the examiner of Patent MX298068 issued three office actions notably stating that “the applicant’s examples prophetically described an alleged technical effect and that the mere mention of the possibility of achieving a result was not experimentally acceptable technical and scientific evidence”.³⁶ The applicant was forced to amend its claims twice in order to obtain the patent, which—although, in my opinion, it was still flawed with a lack of industrial applicability—was granted by the Divisional Director of Patents in 2012, Mr. Salazar.

36. As for Patent 304904, the applicant was required to respond to six office actions regarding the merits of the invention before the patent was granted. The examiner notably stated that “*the application did not describe any experimental technical example showing the technical advantages of the claimed antibody in the treatment of high-grade non-Hodgkin lymphoma, thus, the application is SPECULATIVE regarding the alleged technical effects*”. Since there was no evidence that the invention could solve all the problems originally raised (34) only a patent with a single pharmaceutical use was granted. Although the examiner did not issue a refusal for lack of industrial application expressly, the patent was granted for a use effectively supported in the application as filed.

37. Finally, with respect to Patent MX306302, the claims, as originally submitted, lacked experimental evidence in the description to comply with the industrial applicability

³⁴ During the development of this section I was assisted by Pharmaceutical Biological Chemists Mauricio Caballero and Juan Luis Espinoza.

³⁵ Salazar Second Report, paras. 42-47.

³⁶ Office Action No. 42088, dated June 18, 2010 (**R-459**).

requirement.³⁷ It is only after the applicant filed new set of claims limiting its original claims that the patent was granted.

VII. Challenges to Patent Validity Are Not Common Before Mexican Courts

38. Ms González cites to my First Report to argue that I have understated the number of patent validity challenges before IMPI and that I have misrepresented some of the systemic limitations that lead to the low number of claims.³⁸ Contrary to what she suggests, my first report provides an overview of the institutional context of Mexican patent law.³⁹ Not only do I discuss the different procedures before IMPI,⁴⁰ but I also describe the constraints inherent to patent litigation before Mexican courts.⁴¹ Ms. González mistakenly quotes my statements relating to Mexican courts to support her claims based upon her experience at IMPI.⁴² I therefore stand by my conclusions in this respect from my First Report.

39. Further, Ms. González's claims about the amount of patent disputes at IMPI are wrong. The percentages she refers to do not reflect in the least the numbers that were provided to my firm by IMPI's transparency department in response to Access to Information Requests. Ms. González claims that a large percentage of nullity proceedings before IMPI involve patents.⁴³ While it is true that nullity proceedings involving industrial property rights are regularly litigated before IMPI,⁴⁴ over the last fourteen years, less than 3% of nullity proceedings involved patents.⁴⁵ Ms. González also states that 20% of the 5000 cases that were resolved while she was head of litigation, were patent cases – according to

³⁷ In its office actions, the examiner stated that the description did not contain elements or technical and scientific evidence acceptable by way of practical examples.

³⁸ González Second Report, paras. 50-51.

³⁹ Lindner First Report, paras. 71-88.

⁴⁰ Lindner First Report, paras. 71-77.

⁴¹ Lindner First Report, paras. 78-81, 86.

⁴² González Second Report, para. 56.

⁴³ González Second Report, para. 54.

⁴⁴ González Second Report, para. 53.

⁴⁵ For instance, from the 730 nullity proceedings filed last year, only twenty-one were challenges to patents. In 2013, only twenty-six of the 741 nullity proceedings filed were related to patents. See IMPI's report addressing the Access to information requests (*Solicitudes de Informacion*) 1026500122115 (**R-460**) and 1026500092715 (**R-461**).

Ms. González, this would amount to at least 250 patent validity challenges resolved per year. This is surprising since on average, less than 13 patent validity challenges proceedings were filed every year over the same period.⁴⁶

40. Ms. González may be right that, in absolute terms, there are not many patent cases raising industrial applicability, but that is simply because, contrary to what she suggests based on her recollections, there are relatively few nullity proceedings involving patents. Ms. González is reading too much into the two examples I cited of a patent examiner raising the issue of industrial applicability.⁴⁷ The fact that I only point to two cases in my first report does not show that the requirement sets a low bar; rather it shows that industrial applicability is raised in the very few patent nullity proceedings that are initiated.⁴⁸

VIII. Had the Claimant's Patents Been Challenged Under the Industrial Applicability Requirement, they would have been Invalidated⁴⁹

41. Mr. Salazar disagrees with my previous analysis of the validity of plaintiff's patent MX173791. He notably contends that examples are never required to evaluate industrial application, and as such the examiner in the case of patent MX173791 did not raise an objection because there was no need to include experimental examples.⁵⁰ I beg to differ, the patent description should have contained adequate experimental evidence to establish industrial applicability (i.e. that the claimed compound (olanzapine) had fewer toxic effects in relation to the compounds of similar chemical structures). The claims in Patent 173791 sought to protect the use of olanzapine in treating all kinds of patients with disorders of the central nervous system, including schizophrenia; however these claims

⁴⁶ González Second Report, para. 51.

⁴⁷ Lindner First Report, para. 61; González Second Report, para. 56.

⁴⁸ Ms. Gonzalez underestimates the examples I mention in my First Report because both patents "ultimately issued". However, she does not mention that in both cases the applicants amended the claims to overcome the objections, and in the second case (MX/a/2010/004974) the applicant argued that the support of the alleged therapeutical effect was duly evidenced in the application. With respect to this second case Mr. Salazar transcribed just a part of one of the applicant's response which does not reflect the complete reasoning that justified the issuance of the patent (Mr. Salazar Second Report, para. 33).

⁴⁹ During the development of this section I was assisted by Pharmaceutical Biological Chemists Mauricio Caballero and Juan Luis Espinoza.

⁵⁰ Salazar Second Report, paras 52, 54. See notably the Spanish version of his report where he refers to the requirement to exemplify the utility of the invention.

were only supported by a very limited and inconclusive study.⁵¹ Thus an examiner should have concluded to a lack of industrial applicability, insufficiency of disclosure and lack of support.

42. Mr. Salazar also disagrees with my previous analysis of the validity of plaintiff's patent MX202275. Again he argues that practical examples are only required when the description is unclear and since there was a description of the effective dosage to establish a treatment for ADHD, there was no need to provide experimental evidence.⁵² As a matter of fact, the application did not contain at all experimental information supporting the claims.⁵³ The applicant merely prophesied that atomoxetine would be useful in the treatment of ADHD. Given the applicant's failure to establish industrial applicability, the patent should not have been granted.

Signed at MEXICO, D.F. on: DECEMBER 7, 2015

[signed]
Hedwig A. Lindner López

⁵¹ John Crilly. "The history of clozapine and its emergence in the US market: a review and analysis", *History of psychiatry*, 2007 Vol. 18(1), pp. 39-60 (R-410).

⁵² Salazar Second Report, para 56.

⁵³ The ability of a drug to treat, cure or prevent a disease or condition cannot in any way be deduced or predicted from i.e. a chemical formula or the physiochemical characteristics of the substance. It is impossible to know whether a chemical product resolves a health problem by curing or preventing a disease, or has an improved therapeutic or technical effect, or unexpected synergistic qualities, etc., without referring to some type of scientific data. *See also* Lindner First Report, para 98.

ANNEX I

The following paragraphs are a translation of the Congressional Declaration of Purpose of the 2010 Reform (**R-283**) and of the Congressional Study of the Senate of the 2010 Reform (**R-276**) with emphasis added to show the portions omitted by Ms. Gonzalez in her analysis of the relevance of the 2010 legislative amendments.

Congressional Declaration of Purpose of the 2010 Reform

P. 4-5: "[...] **the industrial application, relates to the function of the invention.**" In other countries this requirement is called "utility" and aims precisely to the fact that **invention sought for patent generates a specific and defined benefit from the moment in which same is conceived.**

Despite the apparent precision of these requirements, in the practice, the latter - the industrial application, has subverted. **Frequently, there are patents formalities wherein the applicant does not accurately define the utility of the invention and same is bypassed if the other two requirements are met.**

To postpone the definition of industrial applicability for stages subsequent to the filing of the application may involve the unsuccessful use of spaces and material and administrative resources, or well, there will be the risk of granting inadequate patents that become obstacles for parallel or future developments.

This is why this amendment proposes to recover and reassess the fulfillment with this essential requirement, as well as to prevent the improper practice of filing patent applications for guaranteeing a filing date, knowing that the development has not been completed. This scheme distorts the purpose of the requirement and induces a practice which, instead of focusing on the comprehensive development of inventions, encourages the filing of poorly supported applications, aiming to fine tune same during their processing, which ultimately alters the purposes of the patent system.

This amendment will promote that the drafting of the description and claims, attached to the patent applications, is more precise, clear and enough so that a skilled technician in the art may develop said invention and improve it when it reaches its expiration date, renewing and improving the technology, which is one of the purposes of the international system of Industrial Property".

Congressional Study of the Senate of the 2010 Reform

P. 5: "Regarding this proposal, it is essential to note that the industrial applicability is the function of the invention, i.e., the practical utility thereof for solving a specific problem or attending a determined situation and it is, along with the novelty and the inventive step, one of the requirements that make an invention "patentable" (article 16).

Regarding the proposed definition, these commissions consider that same is perfectible, considering that when pointing out the invention must "help" in solving a technical problem, it is **a subjective element which would subject the existence or not of the industrial applicability**

itself to discretion. Thus, the introduction of elements such as: " help in practically solving a specific problem" without the establishment of parameters of the degrees of "help" **required for the invention to be awarded with the granting of a letters patent,** may result counterproductive when opening the provision to subjective criteria and to the discretion of the reviewer authority, thus creating legal uncertainty among the users of the industrial property system. For this reasons, these commissions consider to adjust the proposed wording for including that the corresponding invention **"has a practical utility" with which it is deemed that the need of foreseeing said utility** would be attended, without the introduction of elements which could result in discretion or in the generation of confusion.

On the other hand, the modification of the concept “possibility” with “fact” is a drawback and is contrary to the provisions of the Agreement on the Aspects of the Intellectual Property Rights Related with Commerce (hereinafter ADPIC), international document from which Mexico is a part and that was published on the Official Gazette of the Federation on December 30, 1984. Said Agreement provides that the industrial application is a “possibility” and not a “fact”.

It is noted that in case of including the term “fact” same should be necessarily proven, forcing the authority even to the reproduction of the invention, for showing the existence (fact) of the referred industrial application. Likewise, a denial of the existence thereof by the authority would also be difficult to show and motivate for the administrative authority, which in any case should mean an extension to the resolution times of the patent applications, in prejudice of the users of the intellectual property system and to the diligence this procedures are worth of.

Notwithstanding the above, it is considered that the final addition to section IV contained in the initiative that establishes "for the purposes described in the application", satisfies the grounds of the proposed amendment, which aims to limit the practice of filing patent applications which have not concluded the development of the industrial applicability, in order to warrant a filing date, without having specified the utility of the invention."

In this way, said addition warrants that the possibility of industrial applicability will be forcedly linked to the purposes established in the original application, and in case of not demonstrating this possibility, the patent could not be granted."

elemento subjetivo que sometería a discrecionalidad la existencia o no de la propia aplicación industrial. Por lo tanto, el introducir elementos como: ". coadyuve a resolver de manera práctica un problema específico" sin establecer parámetros de los grados de "coadyuvancia" **requeridos para que la invención sea merecedora de obtener un título de patente**, puede resultar contraproducente, al abrir la disposición a criterios subjetivos y a la discrecionalidad de la autoridad revisora, creando incertidumbre jurídica entre los usuarios del sistema de propiedad industrial. Por tal razón, estas comisiones consideran, ajustar la redacción propuesta para incluir que la invención correspondiente **"tenga una utilidad práctica" con lo que se considera se atendería la necesidad de prever dicha utilidad**, sin introducir elementos que pudieran resultar en discrecionalidad o generar confusión.

Por otra parte, modificar en la definición el concepto "posibilidad" por el de "hecho" resulta inconveniente y contrario a lo dispuesto en el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual Relacionados con el Comercio (en adelante AADPIC) instrumento internacional del que México es parte y que fue publicado en el Diario Oficial de la Federación del 30 de diciembre de 1994. En dicho Acuerdo se establece que la aplicación industrial es una "posibilidad" y no un "hecho".

Se advierte que de incluirse el término "hecho" tendría que ser necesariamente objeto de prueba, obligando a la autoridad incluso a reproducir la invención, para demostrar la existencia (hecho) de la referida aplicación industrial. De igual manera, una negativa de la existencia de la misma por parte de la autoridad, sería también de compleja demostración y motivación para la autoridad administrativa, lo que en cualquier caso significaría una prolongación a los tiempos de resolución de las solicitudes de patente, en perjuicio de los usuarios del sistema de propiedad intelectual y de la agilidad que merecen estos procedimientos.

No obstante lo anterior, se considera que la adición final a la fracción IV contenida en la iniciativa que establece "para los fines que se describan en la solicitud" satisface la motivación de la reforma propuesta, que pretende limitar la práctica de presentar solicitudes de patente que no han concluido el desarrollo de la aplicación industrial, con el propósito de asegurar una fecha de presentación, sin haber precisado la utilidad de la invención."

De esta manera dicha adición asegura que se vincule necesariamente la posibilidad de la aplicación industrial con los propósitos que se hayan establecido en la solicitud original, y de no actualizarse esta posibilidad, no podría concederse la patente."