

Questionnaire on Exceptions and Limitations to Patent Rights

The answers to this questionnaire have been provided on behalf of:

Country: **Mexico**
Office: **MEXICAN INSTITUTE OF INDUSTRIAL PROPERTY**

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Section I: General

This section is intended to obtain general information on exceptions and limitations to patent rights that are provided under the applicable laws. For the purpose of this questionnaire, the term “applicable law” refers to relevant national and regional statutory law and, where applicable, case law.

The terms used in the questionnaire are drafted in a general way aiming at providing a broad understanding of each concept used, assuming that the exact wording of these exceptions and limitations might differ under the applicable laws. More detailed explanations of the various exceptions and limitations may be found in the following documents: SCP/13/3, SCP/15/3 and CDIP/5/4.

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

.....
The legal standard used to determine whether an invention is patentable in Mexico is the Law on Industrial Property (LPI), published in the Federation Official Gazette on June 27, 1991, amended by different decrees published on 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, June 18, 2010 and June 28, 2010.

The LPI does not incorporate provisions on patentability, which vary depending on the technology in question, it is simply limited to stating .that “*inventions that are new, involve an inventive step and are industrially applicable shall be patentable...*”

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different

from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.¹

Article 16 of the LPI establishes the following exceptions to patentability:

I. Essentially biological processes for the production, reproduction and propagation of plants and animals;

II. Biological and genetic material as found in nature;
.....

III. Animal breeds;

IV. The human body and the living parts thereof, and

V. Plant varieties.

There is no separate source which establishes exclusions to patentability and, to date, there is no relevant case law.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

.....
The LPI grants to the owner of a patent or his successors in title the following exclusive rights:

a. right of exclusive working of the patented invention by himself or by a third party (Article 9, LPI);

b. right to prevent other persons from manufacturing, using, selling, offering for sale or importing the patented product (Article 25(I) LPI);

c. right to prevent other persons from using the patented process and from using, selling, offering for sale or importing the product obtained directly from that process (Article 25(II) LPI);

d. right to request the administrative declaration of infringement of the rights conferred by the patent (Articles 187, 188 and 213 (II), (XI), (XII), (XIII) and (XXVII) LPI);

e. right to institute a civil liability action for damages caused, through the infringement of patent rights, in which case, the corresponding compensation shall in no case be less than forty per cent of the public sale price of each product that involves an infringement of any of the industrial property rights regulated by the LPI (Article 24, 221, 221bis and 226 LPI);

¹ This question does not imply that the topic of exclusions from patentability is dealt with in this question exhaustively.

- f. right to request the Mexican Industrial Property Office, in relation to the legal procedures relating to the infringement of any of the patent rights, to adopt provisional measures, such as ordering the withdrawal from circulation or preventing this, with respect to the goods that infringe patent rights; prohibit immediately the marketing or use of the products with which a patent right is infringed and ordering the seizure of property (Article 199bis, 199bis 1 LPI);**
- g. right to grant voluntary or contractual licenses, be they exclusive or non-exclusive, for working the patented invention (Article 62 and 63, LPI);**
- h. right to fix and collect royalties for the grant of voluntary or compulsory licenses (Article 15-B Federation Tax Code);**
- i. right to request the nullity of a patent which has been granted for an invention that constitutes an invasion of what has already been patented (Articles 78 and 79, LPI);**
- j. right to assign or transfer totally or partially the rights conferred by the patent (Article 62 LPI).**
- k. right to pay the annuities for maintaining the patent in force, within the six-month grace period (Article 80 (II) LPI);**
- l. right to request and obtain the restoration of the patent, within the six months following the grace period, for the late payment of the corresponding annuities (Article 81 LPI).**

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

- Private and/or non-commercial use;**
- Experimental use and/or scientific research;**
- Preparation of medicines;²**
- Prior use;**
- Use of articles on foreign vessels, aircrafts and land vehicles;**
- Acts for obtaining regulatory approval from authorities;**
- Exhaustion of patent rights;**
- Compulsory licensing and/or government use;**
- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.³**

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other

² For example, extemporaneous preparation of prescribed medicines in pharmacies.

³ For example, in some countries where patent rights extend to propagated or multiplied material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do not constitute patent infringement. Similarly, in some countries, patent rights do not cover uses by breeders of patented biological material for the purpose of developing a new plant variety (see paragraphs 133 to 137 of document SCP/13/3).

parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

**ARTICLE 22. The right conferred by a patent shall not produce any effect against:
I. a third party who, in the private or academic sphere and for non-commercial purposes, carries out purely experimental scientific or technological research, testing or teaching activities, and for that purpose manufactures or uses a product or uses a process equal to that patented;**

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....
N/A.....
.....

6. (a) What are the public policy objectives for providing the exception?

.....
Purely experimental scientific or technological research, testing or teaching activities, involving the manufacture or use of a product or a patented process, within the private or academic sphere and for non-commercial purposes, are activities which promote and foster inventive industrially applicable activity, the technical improvements and the dissemination of technological knowledge within the productive and academic sectors, as stated in Article 2(II) of the LPI.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
N/A.....
.....

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

.....
The industrial property legislation in force does not define what is meant by "non-commercial", "commercial" or "private".

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

.....
N/A.....
.....

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
Since there are no definitions which indicate clearly the scope and content of the exception, it would be advisable to amend the current legal framework......
.....

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

.....
N/A.....
.....

Section III: Experimental use and/or scientific research ⁴

11. If the exception is contained in statutory law, please provide the relevant provision(s):

.....
Article 22(I) of the LPI states the following:

***“Article 22. The right conferred by a patent shall not produce any effect against:
I. a third party who, in the private or academic sphere and for non-commercial purposes, carries out purely experimental scientific or technological research, testing or teaching activities, and for that purpose manufactures or uses a product or uses a process equal to that patented;...”***.....

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....
N/A.....
.....

13. (a) What are the public policy objectives for providing the exception?

.....
Purely experimental scientific or technological research, testing or teaching activities, involving the manufacture or use of a patented product or a process, within the private or academic sphere and for non-commercial purposes, are activities which promote and foster inventive industrially applicable activity,

⁴ Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

technical improvements and the dissemination of technological knowledge within the productive and academic sectors, as stated in Article 2(II) of the LPI......
.....
.....

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
N/A.....
.....

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

.....
Artricle 22 of the LPI refers only to “a third party”, without specifying what the nature of that third party should be, but does state that such a party may carry out experimental, testing or teaching activities with a patented product or process, only in the “private or academic” sphere and for “non-commercial purposes”.
.....

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

.....
The industrial property legislation in force does not define what is meant by “use for experimental purposes”.....
.....

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

- determine how the patented invention works**
- determine the scope of the patented invention
- determine the validity of the claims**
- seek an improvement to the patented invention
- invent around the patented invention**
- other, please specify: **Academic or teaching**

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

- Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
- Research and/or experimentation must be conducted with or using the patented invention (“research with”)
- Both of the above**

Please explain by citing legal provision(s) and/or decision(s):

ARTICLE 22. The right conferred by a patent shall not produce any effect against:

I. a third party who, in the private or academic sphere and for non-commercial purposes, carries out purely experimental scientific or technological research, testing or teaching activities, and for that purpose manufactures or uses a product or uses a process equal to that patented;

V. a third party who, in the case of patents relating to live material, uses the patented product as an initial source of variation or propagation in order to obtain other products, apart from where said use is repeated, and

The performance of any activity envisaged in this Article shall not constitute an administrative infringement or offense in accordance with this Law.....

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

- A non-commercial purpose**
- A commercial purpose
- Both of the above
- The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

.....
Article 22(I) of the LPI refers to “non-commercial purposes”, although the LPI does not provide a definition of what is meant by that concept.....
.....

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

.....
N/A.....
.....

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
The normative case regulated by Article 22(I) of the LPI is sufficient to provide protection to third parties using a patented product or process in the private or academic sphere, for non-commercial and experimental, testing or teaching purposes, a situation for which there is no planned reform or addition to the Law on Industrial Property with respect to this item.....
.....

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

.....
N/A.....
.....

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

.....
N/A.....
.....

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....
N/A.....
.....

25. (a) What are the public policy objectives for providing the exception? Please explain:

.....
N/A.....
.....

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
N/A.....
.....

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

.....
N/A.....
.....

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

- Yes
 No

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

.....
N/A.....
.....

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

.....
N/A.....
.....

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
N/A.....
.....

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

.....
N/A.....
.....

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

.....
Article 22(III) of the LPI states the following:

“Article 22. The right conferred by a patent shall not produce any effect against:

...
.....

III. any person who, prior to the patent application filing, or as appropriate recognized priority, date, uses the patented process, manufactures the patented product or has initiated the necessary preparations to carry out such use or manufacture;

...”
.....

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....
N/A.....
.....

33. (a) What are the public policy objectives for providing the exception? Please explain:

.....
The legislation in force seeks to protect users in good faith so that they may continue using their invention, although a third party not involved therein has obtained a patent for said invention, in order to achieve fairness between two holders of an invention, even though only one of them has patented it......
.....

Similarly, it seeks to protect the user in good faith, provided that such a user may have invested economic, physical and intellectual resources in order to use the invention.

On the other hand, the general legal principle may be considered as follows: “first in time, first in right”.

ARTICLE 10 BIS LPI

Article 10 BIS. The right to obtain a patent or a registration shall belong to the inventor or designer, as the case may be, without prejudice to the provisions of Article 14 of this Law. If the invention, utility model or industrial design has been produced by two or more persons jointly, the right to obtain the patent or the registration shall belong to them jointly.

Where different persons have made the same invention or utility model independently of each other, the person who first files the respective application or who claims the earliest priority date shall have the best right to obtain the patent or the registration, provided that the application is not abandoned or refused.

The right to obtain a patent or registration may be transferred by acts *intra vivos* or by succession.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
N/A.....
.....

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

.....
Article 22 (III) of the LPI establishes quantitative and qualitative limitations to the application of the use by the prior user.

With respect to the quantitative limitations, the Article states that the use must be “earlier” than the patent application filing, or where appropriate recognized priority, date.

In relation to the qualitative limitations, the Article mentions “uses”, “manufactures” or “has initiated the necessary preparations to carry out such use or manufacture”.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

.....
The LPI does not establish the obligation for payment of remuneration to the patent owner by the prior user......
.....

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

- Yes
- No**

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

- Yes
- No**

If yes, please explain what those conditions are:

.....
N/A.....
.....

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

- Yes
- No**

If yes, please explain the conditions under which such use can continue to apply:

.....
N/A.....
.....

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

.....
No other criteria exist......
.....

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
The normative hypothesis established by Article 22(III) of the LPI is sufficient to protect users in good faith of a patented product or process, and so there is no draft amendment or addition to the Law on Industrial Property in relation to this item......
.....

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

.....

None.....
.....

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

.....
Article 22(IV) of the LPI states:

“Article 22. The right conferred by a patent shall not produce any effect against:

IV. the use of the invention in question in vehicles of other countries that form part thereof, where such vehicles are in transit in the national territory; ...”

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....
N/A.....
.....

44. (a) What are the public policy objectives for providing the exception? Please explain:

.....
The aim of the exception being considered is that the Mexican State guarantees the operation of international transport.

.....
(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
N/A.....
.....

45. The exception applies in relation to:

- Vessels**
- Aircrafts**
- Land Vehicles**
- Spacecraft**

46. In determining the scope of the exception, does the applicable law apply such terms as “temporarily” and/or “accidentally” or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

.....
Article 22(IV) of the LPI uses the terms “in transit”. However, the legislation under discussion does not provide a definition of that term, and leaves it to the interpretation of the authority responsible for its application......
.....

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

.....
NO.....
.....

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

.....
N/A.....
.....

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
The exception is adequate and guarantees the operation of international transport; no amendments to the legislation in force are planned......
.....

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

.....
N/A.....
.....

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

.....
With regard to this point, it should be noted that regulation of this type is covered by rules separate from the Law on Industrial Property, specifically in the Regulations on Materials for Health, Article 167bis (introductory part) of which refers to the so-called Bolar Clause, as a regulatory exception, and states:

“...Without prejudice to the provisions of the two previous paragraphs, the registration of a generic medicine may be requested, the active substance or ingredient of which is protected by a patent, in order to carry out the corresponding studies, tests and experimental production, within the three years prior to expiry of the patent. In this case, health registration shall be granted only when the validity of the patent ends.”

The information referred to in Articles 167 and 167bis of these Regulations, which is confidential or reserved in accordance with the provisions of the international treaties to which Mexico is a party and with the other applicable legal provisions, shall be protected against any disclosure to other individuals."

This Article contains the express reference to the nature of the medicine for which registration is requested, i.e. it states that it is an "allopathic medicine", as indicated in Article 224 of the General Health Law, under the classification heading "By their nature", which is reproduced for quick reference:

"Article 224. Medicines are classified

B. By their nature:

1. Allopathic: Any substance or mixture of substances of natural or synthetic origin, that has a therapeutic, preventive or rehabilitatory effect, that is pharmaceutical in form and is identified as such by its pharmacological activity, physical, chemical and biological characteristics, and is registered in the Pharmacopeia of Mexico for allopathic medicines,..."

Article 30 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is also included within the regulatory framework and states:

"Article 30

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....
The exception is not provided through case law.

53. (a) What are the public policy objectives for providing the exception? Please explain:

.....
Authorizing the manufacturers of generic medicines who are beginning the studies, tests and experimental production of the medicines protected by a patent, close to entering the public domain, which will guarantee that, at the time the patent rights expire, the consumer public may opt to acquire the medicine from the firm which owned the patent, or through a third party laboratory at a more competitive price.

The possibility that at the end of the patent's validity, the generic version of the medicine may enter the market and the validity of the patent may not be maintained artificially until such time as all the necessary tests are carried out in order to guarantee the bioequivalence, safety or effectiveness of the generic medicine.

-
(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
There are no such references.

54. Who is entitled to use the exception? Please explain:

.....
Any person who meets the requirements of the Regulations on Materials for Health, established for obtaining a generic medication registration, and requests the registration of an allopathic medicine......

55. The exception covers the regulatory approval of:

- any products
- certain products.** Please describe which products: **Allopathic medicines, whose active substance or active ingredient is protected by a patent, provided that it is within the three years prior to the expiry thereof.**.....

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

- Making**
- Using**
- Selling
- Offering for sale
- Import**
- Export
- Other. Please specify:.....

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

.....
No other criteria are envisaged......

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
The exception is adequate and there are no plans to amend the legislation in force, owing to the fact that a balance is achieved between the public interest and the private interest, since the patent is not infringed as long as it is valid and, when launching the generic version, the interested party may carry out the necessary studies and tests to prepare the product that he will launch on the market until the validity of the patent ends for a reasonable period of time.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

.....
There is no problem since where the third party makes available to the public the product that is protected by a patent, the patent owner may immediately take the appropriate legal action and request, within the patent infringement proceedings, that the product be seized as a precautionary measure......
.....

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

- National
- Regional
- International**
- Uncertain, please explain.....

If the exception is contained in statutory law, please provide the relevant provision(s):

“Article 22. The right conferred by a patent shall not produce any effect against:

...
.....

II. any person who markets, acquires or uses the product patented or obtained by the patented process, immediately after said product has been lawfully marketed;
...”
.....
.....

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....
N/A.....
.....

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

.....
The main aim of this exception is to guarantee the free circulation of goods that have been marketed lawfully, which will produce greater competition within the national market, and benefit consumers with lower prices, but above all clearly signal the prerogatives of the patent owner......
.....

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
In January 2005, the Plenum of the Higher Chamber of the Federal Court of Fiscal and Administrative Justice issued the following opinion in relation to the exhaustion of the right conferred by a patent, which reaffirmed the application of Article 22(II) of the LPI:

Registration No.: 40,326

Closed

Period: Fifth

Authority: Plenum

Source: R.T.F.J.F.A. Fifth Period, Year V. No.58. October 2005.

Report: V-TASS-221

Page: 454

LAW ON INDUSTRIAL PROPERTY

PATENTS. CASE IN WHICH THE USER OF AN INVENTION DOES NOT INFRINGE THE INDUSTRIAL PROPERTY RIGHTS OF THE OWNER.

Where in the administrative dispute hearing, the aspect relating to the use of a patented article by a third party without the patent owner's consent is the subject of the dispute, it is essential to specify which acts are alleged to have infringed the industrial property rights, as well as the person or transaction to which they are attributed, and should the person concerned endeavor to introduce lawfully acts performed by a person other than that examined during the administrative proceedings in which the challenged decision is upheld, as might be the case with the business from which the third party user concerned acquires the protected property, the supposed infringement committed by that provider, this may in no way imply extensive liability on the part of the user, since there are no legal grounds to sanction the person acquiring the property, if he uses it once it has been lawfully marketed, exclusively for the conduct of activities specific to his field, without it being marketed. (2)

Hearing No. 8622/02-17-01-7/399/03-PL-10-04. Settled by the Plenum of the Higher Chamber of the Federal Court of Fiscal and Administrative Justice, at the session of January 14, 2005, by a majority of four votes in favor and three votes against. Presiding Judge: Guillermo Domínguez Belloc. Secretary: Gabriela Badillo Barradas.

(Ruling approved at the hearing of January 17, 2005).

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

- Yes
 No
 Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

.....
Article 25(I) and (II) of the LPI states the following:

"Article 25. The exclusive right to work the patented invention shall confer on its owner the following prerogatives:

I. Where the subject matter of the patent is a product, the right to prevent other persons from manufacturing, using, selling, offering for sale or importing the patented product, without his consent, and

II. Where the subject matter of the patent is a process, the right to prevent other persons from using that process, and from using, selling, offering for sale or importing the product obtained directly from that process, without his consent...”

Notwithstanding the fact that mechanisms exist to support the patent rights owner in preventing the import of patented products or products obtained directly from a patented process, those products shall not invalidate the doctrine adopted by Mexico in relation to the exhaustion of patent rights, provided that the import into Mexico of products patented or obtained directly from a patented process does not constitute an infringement as per Article 213 of the LPI.

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

.....
Yes, it is considered adequate, since the rights of the patent owner are observed and an excess situation avoided whereby any person who later uses the patented product or process has once again to pay for the corresponding royalties. The exhaustion regime for patent rights in Mexico is adequate for achieving the aim of guaranteeing the free circulation of goods and generating greater competition within the domestic market, thereby placing that objective above the interests specific to the owners of patent rights and of the authorized distributors and/or licensees, with the main beneficiary being the Mexican consumer public which obtains genuine products.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

.....
N/A.....
.....

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

.....
With respect to “Compulsory Licenses”, Articles 70 and 77 of the LPI state the following:

Article 70. In relation to inventions, after three years beginning from the date of the patent grant, or four years from the application filing, whichever comes later, any person may request the Institute to grant a compulsory license for working the patent, where such working has not taken place, unless duly justified reasons exist therefor.

The grant of a compulsory license shall not be made, where the patent owner or any person who has a contractual license granted has been importing the product patented or obtained by the patented process.

Article 77. For reasons of national emergency or security and as long as such reasons exist, including serious diseases declared as a priority by the General Health Council, the Institute shall, by means of a declaration to be published in the Federation Official Gazette, decide that certain patents are worked through the grant of public utility licenses, in the cases in which, where this is not done, the production, provision or distribution of basic essentials or medicines for the population is prevented, obstructed or made more expensive.

In cases of serious diseases which are the cause of an emergency or a threat to national security, the National Health Council shall declare such to be a priority, at its own initiative or at the written request of national institutions specializing in diseases, which are accredited by the Council, in which the need for priority attention is justified. Once the Council Declaration has been published in the Official Federation Gazette, pharmaceutical firms may request the grant of a public utility license from the Institute, which shall grant such a license, subject to a hearing with the parties, as soon as the case merits it, in accordance with the opinion of the General Health Council, within a maximum period of 90 days, beginning from the date of filing the application with the Institute.

The Health Secretariat shall fix the conditions for production and quality, duration and scope of the license in question, and also the characterization of the applicant's technical capacity. The Institute shall fix, by listening to both parties, a reasonable amount for the royalties payable to the patent owner.

The grant shall cover one or all of the prerogatives, to which Article 25(I) or (II) of this Law refer.

Apart from the grant of public utility licenses, to which the second and third paragraphs of this Article refer, for the grant of the other licenses the terms of the second paragraph of Article 72 shall be adopted. None of the licenses considered in this Article may be exclusive or transferable.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....
N/A.....
.....

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

- Non-working or insufficient working of the patented invention**
- Refusal to grant licenses on reasonable terms**
- Anti-competitive practices and/or unfair competition
- Public health**
- National security**
- National emergency and/or extreme urgency**
- Dependent patents
- Other, please specify:

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

.....
An attempt is made to avoid misuse on behalf of patent owners, with respect to the exclusivity that patents give them; similarly, said exception contributes to the transfer and dissemination of technology, which basically serves the general interest and informs consumers of the advantage of having a patented product or process on the market within their reach, although it is not on behalf of the patent owner.
The use of the technology for the benefit of the economy and, on the other hand, the preservation of national health and security as the supreme interest above and beyond all the rights of the patent owner.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
N/A.....
.....

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

.....
There is no specific definition of the terms “non-working” or “insufficient working”, although the specific provisions state that working is to be understood not to have taken place, in the case of patents, after three years beginning from the date of grant of the patent and, in the case of applications, the period is four years beginning from the application filing.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

In actual fact, Article 70 of the LPI states that a compulsory license shall not be granted, where the patent owner or any person who has a contractual license granted, has been importing the product patented or obtained by the patented process.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes
 No

If yes, what is the time period?

After three years beginning from the date of grant of the patent and, in the case of applications, the period is four years beginning from the application filing.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

- Yes
- No

If yes, what are "legitimate reasons"?

Article 70 of the LPI states:

Article 70. In relation to inventions, after three years beginning from the date of the patent grant, or four years from the application filing, whichever comes later, any person may request the Institute to grant a compulsory license for working the patent, where such working has not taken place, unless duly justified reasons exist therefor.

A compulsory license shall not be granted, where the patent owner or any person who has a contractual license granted has been importing the product patented or obtained by the patented process.

As may be appreciated, Article 70 of the LPI uses the terms "duly justified reasons", which leaves the owner with the possibility of demonstrating to the Mexican Institute of Industrial Property the reasons for non-working.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

.....
No such definitions.
.....

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

.....
No such practices.
.....

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

.....
No such conditions.
.....

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

.....
Article 72. Before granting the first compulsory license, the Institute shall give the patent owner the opportunity, within a period of one year, beginning from the personal notification given to the owner, to undertake working of the patent.

Subject to a hearing with the parties, the Institute shall take a decision on the grant of the compulsory license and, where it decides to grant such a license, shall fix its duration, conditions, scope and amount of the royalties payable to the patent owner.

Where a compulsory license is requested and another such license exists, the person who has the previous license shall be notified and heard.

In accordance with the provisions of Article 72 of the LPI, the Mexican Institute of Industrial Property shall be responsible for deciding the amount of the royalties for the grant of a compulsory license, in accordance with the opinion of the licensor and licensee.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Article 77 of the LPI establishes the grant of public utility licenses for reasons of national emergency or security.

A case of national emergency or security shall exist where a serious disease is declared to be a priority by the General Health Council, in which case the Mexican Institute of Industrial Property shall decide that certain patents are worked through the grant of public utility licenses or, in the cases where this is not done, the production, provision or distribution of basic essentials or medicines for the population is prevented, obstructed or made more expensive.

One example of the application of the aforementioned Article 77 is that which originated with the A(H1N1) influenza epidemic in April 2009, a virus which spread in Mexico City and surrounding areas, causing at least 20 deaths and as of Friday April 24 placing that area on alert; however, it was not necessary to take the step of granting public utility licenses provided that the pharmaceutical companies responsible for the production of the antivirals Tamiflu and Relenza, within the scope of the respective patents, guaranteed the supply of those medicines and, as a result, no actions made access thereto more expensive or obstructed such access.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

.....
To date, no public utility license has been granted in Mexico within the scope of Article 77 of the LPI.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
The exception is adequate and no amendments to the legislation in force are planned......
.....

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

.....
None......
.....

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

.....
N/A.....
.....

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....
N/A.....
.....

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

- Non-working or insufficient working of the patented invention
- Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- Public health
- National security
- National emergency and/or extreme urgency
- Dependent patents
- Other, please specify:

84. (a) What are the public policy objectives for providing government use in your country?

.....
N/A.....
.....

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
N/A.....
.....

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

.....
N/A.....
.....

86. Please indicate how many times and in which technological areas government use has been issued in your country:

.....
N/A.....
.....

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
N/A.....
.....

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

.....
N/A.....
.....

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

.....
Article 22 of the LPI states the following:

V. A third party who, in the case of patents relating to live material, uses the patented product as an initial source of variation or propagation in order to obtain other products, apart from where said use is repeated,

VI. A third party who, in the case of patents relating to products consisting of live material, uses, places in circulation or markets the patented products for purposes that are not multiplication or propagation, after these have been lawfully marketed by the patent owner or the person who has a license granted.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

.....
N/A.....
.....

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

.....
The conventional activity of farmers to use live material as a source of variation (to obtain new varieties) shall not be considered a sanction......
.....

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
N/A.....
.....

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

.....
No interpretations of this kind have been given......
.....

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
The exception is adequate and no amendments to the legislation in force are planned......
.....

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

.....
Particular cases have not occurred but there is great concern regarding the interpretation of the section of Article 22 which relates to the traditional practice of Mexican farmers, and above all as regards transgenic plants, and possible contamination by pollen of traditional crops. This is due to the imminent approval of commercial transgenic crops......
.....

95. If the exception is contained in statutory law, please provide the relevant provision(s):

.....
This is included in the above.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

.....
N/A.....

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

With regard to Article 22(V) of the LPI, the aim is not to hamper technological development, allowing activities that promote and foster inventive industrially applicable activity, technical improvements and the dissemination of technological knowledge within the field of patents relating to live material.

With regard to Article 22(VI) of the LPI, this section envisages the exhaustion of patent rights relating to products consisting of live material, the main aim of which is to guarantee the free circulation of goods that have been lawfully marketed, which will produce better competition within the domestic market, and benefit consumers with lower prices.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
None.....

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

.....
None.....

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....
The exception is adequate and no amendments to the legislation in force are planned.

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

.....
None.....
.....

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

.....
None.....
.....

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

.....
N/A.....
.....

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
N/A.....
.....

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

.....
N/A.....
.....

In addition, in relation to each exception and limitation, please explain:

(iv) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

.....
N/A.....
.....

(v) if there have been any challenges encountered in the practical implementation of the exception in your country:

.....

N/A.....
.....

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

.....
N/A.....
.....

[End of Questionnaire]