

National Patent Administration Argentina

Contents

| | |
|-------------------------------------------------------------------------------------------------------------|----|
| Section 1: General | 1 |
| Section 2: Private and/or non-commercial use | 3 |
| Section 3: Experimental use and/or scientific research | 3 |
| Section 4: Preparation of medicines..... | 4 |
| Section 5: Prior use | 5 |
| Section 6: Use of articles on foreign vessels, aircrafts and land vehicles | 6 |
| Section 7: Acts for obtaining regulatory approval from authorities | 7 |
| Section 8: Exhaustion of patent rights | 7 |
| Section 9: Compulsory licensing and/or government use..... | 8 |
| Section 10: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions..... | 12 |
| Section 11: Other exceptions and limitations..... | 12 |

Section 1: General

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.

Patentability is determined through the application of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments and its Regulations.

An invention is patentable if it is covered by the definition of "invention" contained in the Law on Patents, is new, has inventive step and is capable of industrial application. Furthermore, the product or process for which a patent is being sought must not be covered by the exclusions and exceptions to patentability contained in the Law on Patents and its corresponding Regulations. However, the application must contain a description of the invention that is sufficiently clear and complete to allow a person with average skill in the art to carry it out. Likewise, the application must contain the best method known of carrying out and putting into practice the invention, and the elements used, set out in a clear and precise manner.

The methods and procedures described must be directly applicable to production.

The National Patent Administration's interpretation of the aforementioned legal standards is set out in the Guidelines on Patenting.

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.

Article 6 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments states that: "The following shall not be considered to be inventions for the purposes of this Law:

- (a) discoveries, scientific theories, and mathematical methods;
- (b) literary or artistic works or any aesthetic creation, as well as scientific works;
- (c) plans, rules and methods for the practice of intellectual activity, for games or economic-commercial activities, as well as computer programs;
- (d) the manner of presenting information;
- (e) methods of surgical, therapeutic or diagnostic treatment applicable to the human body and to animals;
- (f) the juxtaposition of known inventions or mixtures of known products, or alteration of the form, dimensions or materials thereof, except where in reality they are so combined or merged that they cannot function separately or where their particular qualities or functions have been modified so as to produce an industrial result not obvious to a person skilled in the art;
- (g) all living material and substances preexisting in nature."

The corresponding regulation states that: "Plants, animals and the essentially biological processes for their reproduction shall not be considered to be patentable material."

Article 7 of the same legal text states that "The following are unpatentable:

- (a) inventions whose exploitation in the territory of the REPUBLIC OF ARGENTINA should be prevented so as to protect public order or morality, the health or life of persons or animals, or to ensure the conservation of plants or the avoidance of serious damage to the environment;
- (b) biological and genetic material occurring in nature or derived therefrom by reproduction, and genetic reproduction processes replicating nature."

The corresponding regulation states that: "THE NATIONAL EXECUTIVE may prohibit the manufacture and commercialization of inventions, the prevention within its territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment."

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?

In accordance with Article 8 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments "The right to the patent shall belong to the inventor or to his assignees, who shall have the right to assign or transfer said right by any lawful means and to conclude licensing contracts. A patent shall confer on its owner the following exclusive rights, without prejudice to the provisions contained in Articles 36 and 99 of the present Law:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from carrying out the acts of: making, using, offering for sale, selling, or importing the product that is the subject matter of the patent;
- (b) where the subject matter of the patent is a process, the owner of a process patent shall have the right to prevent third parties not having the owner's consent from carrying out the act of using the process and the acts of: using, offering for sale, selling, or importing for these purposes the product obtained directly by that process."

Publication of a patent application does not accord exclusive rights to the patent applicant.

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;
- Prior use;
- Experimental use and/or scientific research;
- Preparation of medicines;
- 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.

Section 2: Private and/or non-commercial use

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

Article 36 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments states that: "The right conferred by a patent shall not have any effect against:

(a) a third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented [...]."

5.-6.

[Note from the Secretariat: response was not provided]

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 law does not define those concepts.

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):

No provision is made for any other criteria.

9.-10.

[Note from the Secretariat: response was not provided]

Section 3: Experimental use and/or scientific research

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

In accordance with Article 36 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: "The right conferred by a patent shall not have any effect against:

(a) a third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented."

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

[Note from the Secretariat: response was not provided]

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

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

[Note from the Secretariat: response was not provided]

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:

Article 36 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments specifically states that the entity shall be "A third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented."

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 terms referred to above are not defined under our national laws.

16.-18.

[Note from the Secretariat: response was not provided]

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 36 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments states that: "The right conferred by a patent shall not have any effect against:

(a) a third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented."

20.-22.

[Note from the Secretariat: response was not provided]

Section 4: Preparation of medicines

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

Article 36(b) of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments states that: "The right conferred by a patent shall not have any effect against: [...]

(b) the preparation of medicines by an authorized professional person and by unit following a medical prescription, or acts relating to medicines so prepared."

24.-25.

[Note from the Secretariat: response was not provided]

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

Professional persons authorized to prepare medicines.

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

Yes.

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

In accordance with Article 36(b) of the Law on Patents: "The right conferred by a patent shall not have any effect against: [...]

(b) the preparation of medicines by an authorized professional person and by unit following a medical prescription, or acts relating to medicines so prepared."

28.-30.

[Note from the Secretariat: response was not provided]

Section 5: Prior use

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

Article 101 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments states: "[...] The patent owner shall have the exclusive right to his invention FIVE (5) years after the publication of the present law in the Official Gazette, unless the third party or third parties making use of his invention without his authorization can guarantee the full supply of the domestic market at the same current prices. In such case, the patent owner shall only have the right to receive a fair and reasonable reward from the third parties making use of the patent from the date of its grant to its expiry. In the absence of agreement between the parties, the NATIONAL INDUSTRIAL PROPERTY INSTITUTE shall set said reward under the terms of Article 43. The provisions contained in this paragraph shall be applied unless said paragraph is amended in order to implement decisions of the World Trade Organization (WTO) adopted in accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)/General Agreement on Tariffs and Trade (GATT) with which compliance is mandatory for the Republic of Argentina."

Furthermore, the corresponding regulation states that: "II. – Upon expiry of the transition period, anyone wishing to limit the remedies available to a holder of rights in protected subject matter must have initiated acts of exploitation or have made a significant investment concerning said acts prior to January 1, 1995. In such case, the patent owner shall have the right to receive the reward provided for under Article 102(3) of the Law. Authorization may not be granted if the patent owner guarantees full supply of the domestic market at the same current prices. The provisions of this paragraph shall be applied unless said paragraph is amended in order to implement decisions of the World Trade Organization (WTO) with which compliance is mandatory for the Republic of Argentina."

32.-34.

[Note from the Secretariat: response was not provided]

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

Under Article 101 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: "The patent owner shall have the exclusive right to his invention FIVE (5) years after the publication of the present law in the Official Gazette, unless the third party or third parties making use of his invention without his authorization can guarantee the full supply of the domestic market at the same current prices. In such case, the patent owner shall only have the right to receive a fair and reasonable reward from the third parties making use of the patent from the date of its grant to its expiry. In the absence of agreement between the parties, the NATIONAL INDUSTRIAL PROPERTY INSTITUTE shall set said reward under the terms of Article 43..."
In turn, the corresponding regulation states that: "II. – Upon expiry of the transition period, anyone wishing to limit the remedies available to a holder of rights in protected subject matter must have

initiated acts of exploitation or have made a significant investment concerning said acts prior to January 1, 1995. In such case, the patent owner shall have the right to receive the reward provided for under Article 102(3) of the Law. Authorization may not be granted if the patent owner guarantees full supply of the domestic market at the same current prices. The provisions of this paragraph shall be applied unless said paragraph is amended in order to implement decisions of the World Trade Organization (WTO) with which compliance is mandatory for the Republic of Argentina.”

36.-41.

[Note from the Secretariat: response was not provided]

Section 6: 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):

In accordance with Article 36(d) of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: “The use of inventions patented in our country on foreign land vehicles, vessels or aircrafts accidentally or temporarily travelling in the jurisdiction of the REPUBLIC OF ARGENTINA, if they are used exclusively for the needs of said vehicles.”

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

The exception is provided through the Law on Patents.

44.

[Note from the Secretariat: response was not provided]

45. The exception applies in relation to:

*Vessels;
Aircraft;
Land vehicles.*

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):

Yes, Article 36(d) of the Law on Patents states the following: “The use of inventions patented in our country on foreign land vehicles, vessels or aircrafts accidentally or temporarily travelling in the jurisdiction of the REPUBLIC OF ARGENTINA, if they are used exclusively for the needs of said vehicles.”

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):

Yes, Article 36(d) of the Law on Patents states the following: “The use of inventions patented in our country on foreign land vehicles, vessels or aircrafts accidentally or temporarily travelling in the jurisdiction of the REPUBLIC OF ARGENTINA, if they are used exclusively for the needs of said vehicles.”

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):

No provision is made for any other criteria.

49.-50.

[Note from the Secretariat: response was not provided]

Section 7: Acts for obtaining regulatory approval from authorities

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

Article 8 of Law 24.766 states that: "In the case of a product or procedure that is protected by a patent, any third party may use the invention prior to the expiry of the patent, for experimental purposes and in order to collect the information required for the approval for marketing of a product or procedure by the competent authority after the expiry of the patent."

52.-53.

[Note from the Secretariat: response was not provided]

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

In accordance with the legislation currently in force: "...any third party may use the invention prior to the expiry of the patent, for experimental purposes and in order to collect the information required for the approval for marketing of a product or procedure by the competent authority after the expiry of the patent."

55. The exception covers the regulatory approval of:

All products.

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

"In the case of a product or procedure that is protected by a patent, any third party may use the invention prior to the expiry of the patent, for experimental purposes and in order to collect the information required for the approval for marketing of a product or procedure by the competent authority after the expiry of the patent."

57.-59.

[Note from the Secretariat: response was not provided]

Section 8: Exhaustion of patent rights

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

International.

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

In accordance with Article 36(c) of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments "The right conferred by a patent shall not have any effect against: (c) Anyone acquiring, using, importing or in any way marketing the patented product or the product obtained by means of the patented process, after said product has been lawfully placed on the market in any country. It shall be understood that the marketing is lawful if it is in accordance with Part III, Section 4 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)/General Agreement on Tariffs and Trade (GATT)."

And the corresponding regulation states that: "For the purposes of Article 36(c) of the Law, the owner of a patent granted in the REPUBLIC OF ARGENTINA shall have the right to prevent third parties from carrying out acts of manufacturing, using, offering for sale or importing into the territory the product the subject of the patent without his authorization, as long as said product has not been lawfully placed on the market in any country.

The product shall be deemed to have been lawfully placed on the market when the licensee authorized to market it in the country shall prove that he has been so authorized by the owner of the patent in the country of acquisition, or by a third party authorized to market the product. The marketing of the imported product shall be subject to the provisions of Article 98 of the Law and this Regulation."

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

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

[Note from the Secretariat: response was not provided]

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?

In accordance with Article 8 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments "A patent shall confer on its owner the following exclusive rights, without prejudice to the provisions contained in Articles 36 and 99 of the present Law: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from carrying out the acts of: making, using, offering for sale, selling, or importing the product that is the subject matter of the patent; (b) where the subject matter of the patent is a process, the owner of a process patent shall have the right to prevent third parties not having the owner's consent from carrying out the act of using the process and the acts of: using, offering for sale, selling, or importing for these purposes the product obtained directly by that process."

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

Yes.

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

[Note from the Secretariat: response was not provided]

Section 9: Compulsory licensing and/or government use

Compulsory licenses

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

Provision is made for compulsory licenses in Articles 42 to 50 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments, under the heading "Other uses without the authorization of the patent owner".

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

[Note from the Secretariat: response was not provided]

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*

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

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

[Note from the Secretariat: response was not provided]

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):

In accordance with Article 43 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: "Once THREE (3) years have elapsed following a patent grant, or FOUR (4) years following the filing of the application, except in the case of force majeure, if the invention has not been exploited or if effective and serious preparations have not been made to work the patented invention or if the exploitation of the patented invention has been interrupted for more than ONE (1) year, any person may apply for authorization to use the invention without the authorization of its owner. Objective difficulties of a technical and legal character, such as delays in obtaining registration for marketing approval from Public Bodies, which are beyond the patent owner's control and which make the exploitation of the invention impossible, shall be considered as force majeure in addition to those circumstances legally recognized as such. The lack of financial resources or the lack of financial feasibility of the exploitation shall not alone constitute justification [...]."

While the corresponding regulation states that: "Exploitation of a product shall be deemed to take place if distribution and marketing are carried out on a scale sufficient to satisfy the demands of the domestic market, under reasonable commercial conditions [...]."

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):

[Note from the Secretariat: response was not provided]

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.

If yes, what is the time period?

In accordance with Article 43 of the Law on Patents “Once THREE (3) years have elapsed following a patent grant, or FOUR (4) following the filing of the application [...].”

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?

The reasons concerned must be reasons of force majeure, the Law stating in this regard that: “Objective difficulties of a technical and legal character, such as delays in obtaining registration for marketing approval from Public Bodies, which are beyond the patent owner's control and which make the exploitation of the invention impossible, shall be considered as force majeure in addition to those circumstances legally recognized as such. The lack of financial resources or the lack of financial feasibility of the exploitation shall not alone constitute justificatory circumstances [...].”

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):

In accordance with Article 42 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: “Where a proposed user has made efforts to obtain a license from the owner of the patent under reasonable commercial terms and conditions under the terms of Article 43 and such efforts have not been successful following a period of ONE HUNDRED AND FIFTY (150) consecutive days as of the date on which the corresponding license was requested, the NATIONAL INDUSTRIAL PROPERTY INSTITUTE may allow other uses of that patent without the authorization of its owner. Without prejudice to the above information, there is an obligation to notify the authorities established by Law No. 22.262, or the law amending or replacing Law No. 22.262, which protects free competition for the corresponding purposes.”

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):

In accordance with Article 44 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: “The right to exploitation conferred by a patent shall be granted, without the authorization of its owner, if the competent authority has determined that the patent owner engaged in anti-competitive practices. In such cases, without prejudice to the remedies available to the patent owner, the grant shall be carried out without the need to implement the procedure set out in Article 42. For the purposes of the present law, the following, inter alia, shall be deemed to be anti-competitive practices:

- (a) the fixing of excessive or discriminatory prices for patented products in relation to average market prices; in particular, where offers of market supply exist at prices significantly lower than those offered by the owner of the patent for the same product;*
- (b) the refusal to supply the local market under reasonable commercial conditions;*
- (c) the obstruction of commercial or production activities;*
- (d) any other act that falls into the category of behavior deemed to be punishable under Law No. 22.262 or the Law replacing or substituting that Law.”*

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:

In accordance with Article 46 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: "The use without authorization of the patent owner to permit the exploitation of a patent –the second patent- which cannot be exploited without infringing another patent –the first patent- shall be granted provided that all the following conditions are met:
(a) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
(b) the owner of the first patent shall be entitled to obtain a cross-license on reasonable terms to use the invention claimed in the second patent; and
(c) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."

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:

In accordance with Article 47(h) of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: "Where other uses are permitted without the authorization of the patent owner, the following provisions shall be observed:
(h) the rightholder shall be paid reasonable remuneration in the circumstances of each case, taking into account the economic value of the authorization, following the procedure contained in Article 43; when determining the amount of the remunerations in cases in which the uses were authorized in order to remedy anti-competitive practices, the need to correct said practices must be taken into account and termination of authorization may be refused if it is felt that it is probable that the conditions which led to a license being granted are likely to recur;"
Furthermore, Article 48 of the same legal text adds that: "In all cases the decisions relating to uses not authorized by the patent owner shall be subject to judicial review, along with the issues linked to the remuneration corresponding to the patent owner where appropriate."

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:

In accordance with Article 45 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: "THE NATIONAL EXECUTIVE may for purposes of health emergency or national security order the exploitation of certain patents through the grant of the right to exploit conferred by a patent; the scope and duration of the exploitation shall be limited to the purpose of the grant."
The corresponding regulation adds: "THE NATIONAL EXECUTIVE shall grant compulsory licenses based on the provisions of Article 45 of the Law, with the involvement of the MINISTRY OF ECONOMY AND PUBLIC WORKS AND SERVICES, the NATIONAL INDUSTRIAL PROPERTY INSTITUTE and, if need be, the MINISTRY OF HEALTH AND SOCIAL ACTION or the MINISTRY OF DEFENSE, within the framework of the competences bestowed upon them by the Law on Ministries."

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

No compulsory licenses have been issued.

79.-80.

[Note from the Secretariat: response was not provided]

Government use

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

In accordance with Article 45 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: "THE NATIONAL EXECUTIVE may for purposes of health

emergency or national security order the exploitation of certain patents through the grant of the right to exploit conferred by a patent; the scope and duration of the exploitation shall be limited to the purpose of the grant.”

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

The exception is provided through the Law.

83.-85.

[Note from the Secretariat: response was not provided]

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

There are no data available in this regard.

87.-88.

[Note from the Secretariat: response was not provided]

Section 10: 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):

Our country acceded to the 1978 UPOV Act through Law 24.376, which does not permit cumulative protection. As a consequence, the Republic of Argentina protects plant varieties through Law No. 20.247 on Seeds and Phytogenetic Creations.

90.-93.

[Note from the Secretariat: response was not provided]

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:

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: response was not provided]

Section 11: Other exceptions and limitations

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

In accordance with Article 41 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments: “THE NATIONAL INDUSTRIAL PROPERTY INSTITUTE, following a reasoned request from a competent authority, may establish exceptions limited to the rights conferred by a patent. The exceptions must not unreasonably conflict with the normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.”

Furthermore, the corresponding regulation states that: "The Ministry of Economy and Public Works and Services, together with the Ministry of Health and Social Action or the Ministry of Defense, to the extent that they are competent, shall be the competent authorities concerning requests for the establishment of exceptions limited to the rights conferred by a patent, under the terms and with the limits provided for in Article 41 of the Law".

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):

Law No. 24.481 and subsequent amendments, as well as Article 8 of Law No. 24.766.

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:

[Note from the Secretariat: response was not provided]

[End of Questionnaire]