

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: Dominican Republic.....
Office: National Office of Industrial Property (ONAPI).....

Person to be contacted:

Name: Luisa Arelis Castillo Bautista
Title: Director, Department of Inventions.....
E-mail: l.castillo@onapi.gob.do
Telephone: 809-567-7474 Ext.3450.....
Facsimile: (809) 732-7758.....

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 or legal framework in force used to determine the patentability of a patent application is Law No. 20-00 on Industrial Property.....
.....
.....

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

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

The exclusions from patentability contained in Law No. 20-00 are envisaged in Article 2 (repealed and replaced by Article 1 of Law No. 424-06 of November 20, 2006, the text of which is as follows):

Article 1 – Subject matter excluded from patent protection

(1) The subject matter which does not fit the definition of Article 1 of this Law shall not be considered an invention and shall therefore be excluded from patent protection. In particular, the following are not considered inventions:

(a) Discoveries which consist in making known something which already exists in nature, scientific theories and mathematical methods;

(b) Exclusively aesthetic creations;

(c) Economic or business plans, principles or methods, and those referring to purely mental or industrial activities or games;

(d) Information presentations;

(e) Computer programs;

(f) Therapeutic or surgical methods for human or animal treatment, and also diagnostic methods;

(g) Any class of live material and substances pre-existing in nature, provided that the invention is directed toward the live material or substance in the form in which it exists in nature;

(h) The juxtaposition of known inventions or mixtures of known products, their variation in form, dimensions or materials, apart from in the case of a combination or merger thereof, such that they cannot function separately or that the characteristic features or functions thereof are modified in order to obtain an industrial result not obvious to a person skilled in the art;

(i) Products already patented since a use distinct from that included in the original patent is attributed thereto;

(2) The following inventions shall not be patentable and shall not be published:

(a) Those whose working would be contrary to ordre public or morality;

(b) Those which are obviously contrary to the health or life of people or animals, or may cause serious harm to the environment;

(c) Plants and animals, except for microorganisms, and essentially biological procedures for the production of plants or animals, that are not non-biological or microbiological procedures. Plant varieties shall be regulated by a special law, in accordance with Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

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?

• **According to Article 29 of Law No. 20-00, the rights and protection conferred by a patent are as follows:**

(1) *The patent shall confer on its owner the right to exclude third persons from working the patented invention. With the limitations provided for in this Law, the patent owner shall therefore have the right to act against any person who, without his authorization, performs any of the following acts:*

- (a) *where the patent has been granted for a product;*
- (b) *manufacturing the product;*
- (c) *offering for sale, selling or using the product; importing it or storing it for any of these purposes;*
- (d) *where the patent has been granted for a process;*
- (e) *using the process;*
- (f) *performing any of the acts indicated in (a) with regard to a product obtained directly from the use of the process;*

(2) *The scope of the protection conferred by the patent shall be determined by the claims. The claims shall be interpreted in the light of the description and the drawings and, where appropriate, such biological material as has been deposited.*

In relation to the second part of this question, the publication of an application does not confer exclusive rights on the applicant owing to the fact that the fundamental aim of the publication is to disclose to the public the information contained in the application so that the interested parties may make any observation they consider relevant.

The submission of observations shall not suspend the processing of the application. The observation may be submitted within 60 days following the publication date. See Article 21 of Law No. 20-00 on Industrial Property.

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

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).

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 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 30) of Law No. 20-00. The patent shall not give the right to prevent:

(a) acts performed in the private sphere and for non-commercial purposes;

.....

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

This exception is provided through TRIPS; to date, the Dominican Republic has no case law on this subject......

.....

.....

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

To date, the Dominican Republic has no defined public policy objective for providing this exception; such an exception was included in the legislation, with TRIPS as a reference......

.....

.....

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

There is no relevant case history......

.....

.....

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):

These concepts are not defined in legislation......

.....

.....

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):

Law No. 20-00 (Article 30) establishes the following condition “*The actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties*”

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:

With regard to exceptions, no changes to our legislation have been envisaged.....

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

For the time being no challenges have arisen.

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 30. The patent shall not give the right to prevent:

(b) Acts performed exclusively for the purposes of experimentation with respect to the patented invention;

(c) acts performed exclusively for the purposes of teaching or scientific or academic research.

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

This exception is provided through TRIPS; to date, the Dominican Republic has no case law on this subject.....

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

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

To date, the Dominican Republic has no defined public policy objectives for providing this exception; such an exception was included in the legislation, with TRIPS as a reference

.....
.....

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

There is no relevant legislative case history.

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:

.....
No, legislation does not specify differences as regards the nature of the organization that conducts experiments or research......
.....

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):

.....
These concepts are not defined in our legislation......
.....

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: **Law No. 20-00 (Article 30(b)) of the legislation specifies that the experimentation is with respect to the patented invention.**

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):

Law No. 20-00 (Article 30(b)) of the legislation specifies that the experimentation is with respect to the patented invention......
.....
.....

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):

.....
No distinction is made between these two terms.
.....

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):

.....
The legislation (Article 30) establishes the following condition “*The actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties*”.
.....

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:

With respect to this exception, no changes to our legislation have been envisaged.
.....
.....

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

No challenges to date......
.....
.....

Section IV: Preparation of medicines

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

This exception is not included in legislation......
.....
.....

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 31. Right of the prior user of the invention.
(1) The rights conferred by a patent may not be enforced against a person who, in good faith and prior to the filing date, or where appropriate priority date, of the corresponding patent application, was already in the country producing the product or using the process which constitutes the invention, or had made effective and serious preparations for such production or use.

(2) That person shall have the right to continue producing the product or using the process as he had been doing, or to initiate the production or use that he had planned. This right may be assigned or transferred only with the firm or establishment in which such production or use was being carried out or had been planned.
.....
(3) The exception provided for in this Article shall not apply if the person wishing to make use of it has acquired knowledge of the invention by means of an unlawful act.....

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

.....
There is no source in case law......
.....

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

To date, the Dominican Republic has no defined public policy objective for providing this exception......
.....
.....

(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 31(1) of Law No. 20-00 specifies the following “*producing the product or using the process which constitutes the invention, or had made effective and serious preparations for such production or use.*”.....
.....

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

.....
The legislation does not envisage payment of remuneration to the patent owner. . .
.....

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:

.....
Article 31(2) states the following: “*This right may be assigned or transferred only with the firm or establishment in which such production or use was being carried out or had been planned*”.....
.....

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:

.....
.....
.....

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):

.....
The legislation (Article 30) establishes the following condition: "*The actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties*".
.....

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:

.....
With respect to this exception, no changes to our legislation have been envisaged.
.....

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

.....
No challenges to date.
.....

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):

.....
Not contained in our legislation.
.....

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:

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

(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:

N/A

- 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):

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

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):

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

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:

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

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):

.....

Article 30(g) states “*Those uses necessary to obtain health approval and to market a product following the expiry of the patent that protects it.*”

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

It has no basis in case law......

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

To date, the Dominican Republic has no defined public policy objective for providing this exception.

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

Not possible.

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

Any third party; Article 30 of the legislation does not specify who may or may not use this exception.

55. The exception covers the regulatory approval of:

- any products
- certain products. Please describe which products:

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: **The legislation does not specify the acts authorized, it only specifies “uses necessary to obtain the health approval and to market a product”**.....

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):

.....

Legislation (Article 30) establishes the following condition: *“The actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties”*

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:

.....
With respect to this exception, no changes to our legislation have been envisaged.
.....

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

.....
No challenges have arisen to date......
.....

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 30(d) *“The sale, hire, use, usufruct, import or any form of marketing of a product protected by the patent or obtained by the patented process, once said product has been placed on the market of any country, with the consent of the owner or of a licensee, or in any other lawful manner. The products or processes which infringe industrial property rights shall not be considered lawfully marketed”*.....
.....
.....

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

.....
This exception is provided through TRIPS; to date, the Dominican Republic has no case law on this subject......
.....

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

.....

To date, the Dominican Republic has no defined public policy objectives providing for this exception; such an exception was included in the legislation, with TRIPS as a reference......
.....

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

.....
Not possible......
.....

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):

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

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

.....
There are no public policy objectives on this subject......
.....

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

.....
No problems have arisen to date......
.....

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):

.....
*Article 40 envisages the following on **Compulsory licenses**:*

(1) Where a potential user has tried to obtain the grant of a license from the owner of the patent on reasonable commercial terms and conditions, and such attempts have had no effect at the end of a period of two hundred and ten (210) days, beginning from the date on which the respective license was requested, the National Office of Industrial Property,

subject to a hearing with the owner, may issue compulsory licenses in relation to that patent.

PARAGRAPH. *In all the following cases, the National Office of Industrial Property shall grant compulsory licenses where the interested party shows that:.....*

(a) it possesses technical and economic capacity to deal with the working in question. Technical capacity shall be evaluated by the competent authority, in accordance with the specific standards in force in the country, which exist in each branch of activity. Economic capacity means the possibility to fulfill the obligations stemming from the working to be performed;

(b) where the patent refers to a raw material from which an attempt is made to develop a final product, the applicant may develop the final product by himself or have third parties develop it in the country, apart from the cases where production on the national territory is impossible.

(2) In order to determine what the meaning of reasonable commercial terms and conditions is, the particular circumstances of each case and the economic value of the authorization shall be taken into account, bearing in mind the rate of average royalties for the sector in question, in relation to commercial license contracts between independent parties.

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

.....
This exception is provided through TRIPS; to date, the Dominican Republic has no case law on this subject......
.....

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:

.....
To date, the Dominican Republic has no defined public policy objectives for providing this exception; such an exception was included in the legislation, with TRIPS as a reference......
.....

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

.....
There is no case history......
.....

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):

.....
Legislation does not define as such the terms “non-working” or “insufficient working”, but Article 39 thereof defines what is meant by working of a patent......
.....

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 accordance with Article 39 of the legislation, working of a patent means the following:

(a) Where the patent has been granted for a product or a process to obtain a product, the supply of the internal market in terms of reasonable quantity, quality and price, through production in the country and import;

(b) Where the patent has been granted for a process not covered by (a), the use of the process on a commercial scale in the country.

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?

Article 41(1) of the legislation states that three (3) years must have passed from the grant of the patent or four (4) from the filing of the application, the period which expires later being applied, if the invention has not been worked or where the working thereof has been interrupted for more than one (1) year without due cause.

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 41(2) states the following:

“A compulsory license shall not be granted where it is demonstrated that the non-working or insufficient working is due to chance or force majeure, or circumstances independent of the will or beyond the control of the patent owner and which justify the non-working or insufficient working. The lack of economic resources or the lack of economic viability of the working shall not be considered mitigating 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):

.....
Article 40(2) of Law No. 20-00 states that: *“In order to determine the meaning of reasonable commercial terms and conditions, the particular circumstances of each case and the economic value of the authorization shall be taken into account, bearing in mind the rate of average royalties for the sector in question, in relation to commercial license contracts between independent parties.”*.....
.....

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 Article 42 of the legislation, the following shall *inter alia* be considered anti-competitive practices:

(a) *The fixing of excessive or discriminatory prices for patented products. 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 lack of market supply on reasonable commercial conditions;*

(c) *The obstruction of commercial or production activities;*

(d) *Any other act which national legislation characterizes as anti-competitive, limiting or restrictive of competition.*.....

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 44(c), *Compulsory licenses shall extend to patents relating to the components and processes allowing them to be worked.*

In addition, Article 45 on compulsory licenses in the case of dependent patents states the following:

(1) **Where an invention claimed in a later patent cannot be worked in the country without infringing an earlier patent**, the National Office of Industrial Property, at the request of the owner of that patent or his licensee, or of the beneficiary of a compulsory license for that patent, **may grant a compulsory license with respect to the earlier patent, insofar as it is necessary to avoid the infringement.**

(2) **The compulsory license shall be granted only where the invention claimed in the later patent involves an important technical advance of considerable economic significance with respect to the invention claimed in the earlier patent**

(3) *Where a compulsory license is granted in accordance with (1), in the same circumstances a compulsory license may be granted with respect to the later patent, if the owner of the earlier patent, his licensee, or the beneficiary of a compulsory license for said earlier patent, so requests.*

(4) *A compulsory license from among those provided for in this Article may not be granted exclusively. This compulsory license may only be the subject of a transfer where simultaneously the dependent patent, whose industrial working requires the license, is also transferred. The transfer of the compulsory license shall be subject to the provisions of Article 32(2),as appropriate.*

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 44(g) of Law No. 20-00, "**the patent owner shall receive reasonable remuneration according to the specific circumstances of each case, taking into account the economic value of the authorization**. When determining the amount of the remuneration, **in the cases in which the compulsory licenses have been granted to remedy anti-competitive practices, the need to correct said practices shall be taken into account** and the revocation of the grant may be refused if it is considered that the conditions which gave rise to that grant are likely to recur".
.....

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:

These two concepts are not defined in the legislation.....
.....
.....

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

.....
To date, the Dominican Republic has not granted any compulsory licenses.
.....

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:

.....
We consider the content of the legislation to be adequate and we do not plan to make any changes in this regard.....
.....

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

.....
No challenges have arisen to date......
.....

Government use

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

.....
For reasons of public interest, and in particular for reasons of emergency or national security declared by the Executive Authority, the National Office of Industrial Property shall, at the request of any interested person or competent authority, or ex officio, make provision at any time for the following:

.....
(a) an invention which is the subject matter of a patent or a patent application being processed is worked by a State body or by one or more public or private law persons designated for the purpose; or

(b) an invention which is the subject matter of a patent or a patent application being processed is open to the grant of licenses of public interest, in which case the National Office of Industrial Property shall grant a working license to any person that so requests and has the capacity to carry out such working in the country.

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

.....
.....
.....

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?

.....
To date, the Dominican Republic has no defined public policy objectives providing for this exception; such an exception was included in the legislation, with TRIPS as a reference......
.....

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

.....
Not possible......
.....

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:

.....
These two concepts are not defined in the legislation......
.....

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

.....
To date working by the government has never been authorized in the Dominican Republic......
.....

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:

.....
We consider the content of the legislation to be adequate and we do not plan to make any changes in this regard......
.....

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

.....
No challenges have arisen to date......
.....

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):

This exception is not included in our legislation......
.....
.....

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:

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

- (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):

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

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:

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

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:

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

Breeders' use of patented inventions

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

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

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:

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

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

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

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):

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

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:

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

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:

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

Section XI: Other Exceptions and Limitations

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

.....
They have been expressed......
.....

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:

.....
No other mechanisms exist for the limitation of patent rights......
.....

[End of Questionnaire]