

Questionnaire on Exceptions and Limitations to Patent Rights

[English translation by WIPO]

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

Country: **Democratic Republic of Sao Tome and Principe**
Office: **Servicio Nacional de la Propiedad Industrial (SENAPI) National Industrial Property Service**.....

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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.

Law No. 4/2001, namely the Law on Industrial Property (chapter II, article 3) is the legal standard used to determine whether an invention is patentable.
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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.

Under the provisions of article 2.3 of the Law on Industrial Property, exclusions from patentability include:
discoveries, scientific theories or mathematical methods;
schemes, rules or methods of doing business, performing purely mental acts or playing games;
methods for the surgical or therapeutic treatment of the human or animal body, as well as diagnostic methods relating thereto.....

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?

Under the provisions of paragraph 7.4 of the above-mentioned law, exclusive rights granted via a patent cover:
making, importing, offering for sale, selling, or using the product;
holding onto the product, in order to put it on the market, sell it or use it;
in cases where the patent concerns a process, the use of that process or any of the activities specified above relating to a product directly obtained by that process;

The law in question does not refer to the granting of exclusive rights from the date of publication of the patent application.
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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 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.).

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).

Section II: Private and/or non-commercial use

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

No such provisions exist.....
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5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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

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

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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):

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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):

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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:

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

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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 8.4(c) of Law 4/2001

The protection afforded by a patent does not extend to acts relating to a patented invention for scientific research purposes.

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

No such provisions exist.
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13. (a) What are the public policy objectives for providing the exception?

No such provisions exist.
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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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:

Not applicable.
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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):

No definition is provided.
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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:

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

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:

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):

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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 such provisions exist.....
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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):

No such provisions exist.....
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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:

There are no plans to amend current legislation.....
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22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenges have been encountered.
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Section IV: Preparation of medicines

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

No such provisions exist.....
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24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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

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

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

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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):

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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):

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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:

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

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Section V: Prior use

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

Article 8.4(d) and 8.5 of Law No. 4/2001

The protection afforded by a patent does not cover acts performed by any person who, in good faith, and as at the filing date or the priority date when ownership is claimed for the basic application for which the patent was granted, was using the invention or making effective and serious preparations to use it, within the territory of the Democratic Republic of Sao Tome and Principe, as long as such acts, in their nature or purpose, do not differ from effective prior use or planned prior use .

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Prior user rights may only be transferred to a company or association, or part of the company or association, where the invention was being used or where preparations had been made for its use.

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

No such provisions exist.....
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33. (a) What are the public policy objectives for providing the exception? Please explain:

Not applicable.....
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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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):

Although the law does not define the scope of use, under the provisions of article 8.4 of Law No. 4/2001, the term “use” is defined as follows:

The prior user must have used the invention in good faith.

The invention must have been used within the territory of the Democratic Republic of Sao Tome and Principe;

These actions should, in their nature or aim, not differ from effective prior use or planned prior use. The invention must have been in use, or effective and serious preparations must have been made for its use, prior to the filing date or the priority date of the patent application.....

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

No such provisions exist.....
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36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

No such provisions exist.

- 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:

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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?

No such provisions exist.

- Yes
- No

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

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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 such provisions exist.....
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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:

To date, it has been considered adequate. There are no plans to amend current legislation.
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41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No such challenges have arisen.....
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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 8.4(b) of Law No. 4/2001
The protection conferred by the patent does not cover the use of articles on board foreign aircraft, land vehicles or vessels which temporarily or accidentally enter the national airspace, national territory, or the territorial waters of the Democratic Republic of Sao Tome and Principe.....
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43. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

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

Not applicable.....
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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45. The exception applies in relation to:

- Vessels
- Aircraft
- 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):

The law applies those terms but does not define them.
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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 such provisions exist.....
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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 such provisions exist.....
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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:

To date, the framework has been considered adequate, and there are no plans to amend current legislation.
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50. 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 in this respect.
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Section VII: Acts for obtaining regulatory approval from authorities

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

No such provisions exist.....
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52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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

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

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

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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:.....

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):

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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:

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

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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 8.4 of Law No. 4/2001

The protection conferred by a patent does not cover acts relating to objects offered for sale in the Democratic Republic of Sao Tome and Principe by the patentee, or with their consent.....
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If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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

Not applicable.
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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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):

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

To date, it has been considered adequate.....
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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 challenges have arisen in that respect.....
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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 7.6, 7.7 and 8.2 of Law No. 4/2001:
In cases where the public interest requires it, particularly with regard to national security, food, health or the development of other vital sectors of the national economy, the competent Ministry may decide that, even without the consent of the patentee, a third party appointed by the Ministry, in the service of the State, may “work” the patented invention, providing that compensation is paid to the patentee..
An appeal against the decision of the Ministry may be lodged with the Supreme Court of Justice, which will issue a final ruling on the matter.

If the patented invention is not sufficiently “worked” in the Democratic Republic of Sao Tome and Principe on an industrial scale, the patentee may be forced to accept the granting of a compulsory license to the interested party.....
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66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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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: ...Food and the development of other vital sectors of the national economy.....

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

Not applicable

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

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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):

The law applies those terms but does not provide a definition.....

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):

Yes, under the provisions of article 7.4 of Law No. 4/2001, the “working” of a patented invention involves any of the following:

(b) if the patent was granted by a process:

(I) using the process;

(II) performing the acts mentioned in a) relating to a product which is directly derived from the use of that process

The acts in (a) refer to:

(I) manufacturing, importing, putting on the market, selling or using the product.

(II) holding on to the product with the aim of putting it on the market, selling or using it.

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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?

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"?

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 provisions exist.
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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 provisions exist.
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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 provisions exist.
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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:

Yes. Under the provisions of article 7.6 of Law No. 4/2001, the competent Ministry may decide that, even without the consent of the patentee, a third party appointed by the Ministry, in the service of the State, may "work" the patented invention, provided that compensation is paid to the patentee.

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:

The law does not explicitly use the terms "national emergency" or "circumstances of extreme urgency", but they are implicit in the provisions relating to national security and health contained in

article 7.6 of the above-mentioned law. National security issues could include a military attack or war, and health risks could include the existence of an epidemic or similar situation.....
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78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Never.
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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 applicable legal framework is considered adequate to meet the objectives sought, as the article refers to the granting of a compulsory license if that decision is in the public interest.....
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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 yet arisen.....
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Government use

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

Article 7.6 and 7.7 of Law No. 4/2001

If it is in the public interest, particularly with regard to national security, food, health or the development of other vital sectors of the national economy, the competent Ministry may decide that, even without the consent of the patentee, a third party appointed by the Ministry, in the service of the State, may “work” the invention, provided that compensation is paid to the patentee.

An appeal against the decision of the Ministry may be lodged with the Supreme Court of Justice, which will issue a final ruling on the matter.
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82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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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: Food and the development of other vital sectors of the national economy.....

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

No provisions exist

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

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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:

The law does not explicitly use the terms “national emergency” or “circumstances of extreme urgency”, but they are implicit in the provisions relating to national security and health contained in article 7.6 of the above-mentioned law. National security issues could include a military attack or war, and health risks could include the existence of an epidemic or similar situation.....

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

To date, it has never been authorized.

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:

The applicable legal framework is considered adequate to meet the objectives sought, as the article refers to the granting of a compulsory license if that decision is in the public interest.

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 been encountered so far.....

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):

No such exception exists.....
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90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

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

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

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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):

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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:

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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:

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Breeders' use of patented inventions

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

No such exception exists.....
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96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

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

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

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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):

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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:

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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:

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Section XI: Other Exceptions and Limitations

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

Inventions which are incompatible with public order or propriety.
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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):

Under the provisions of article 3.5 of Law No. 4/2001 – the Law on Industrial Property- inventions incompatible with public order or propriety cannot be patented.....
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(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:

The aim is to maintain public order and propriety in the Democratic Republic of Sao Tome and Principe.
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(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

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

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

It is considered adequate to meet the objectives sought.
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.....

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

No such challenges have been encountered to date.
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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:

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