

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: **Sultanate of Oman**
Office: **Intellectual Property Department**.....

Person to be contacted:

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Section I: General

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

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

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

The legal standard used is that the invention meets the three conditions for granting (Novelty, Inventive step and industrial applicability)

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) The following shall be excluded from patent protection:
(a) Discoveries, scientific theories and mathematical methods;

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

- (b) **Schemes, rules or methods for doing business, performing purely mental acts or playing games;**
- (c) **Natural substances; this provision shall not apply to the processes of isolating those natural substances from their original environment;**
- (d) **Known substances for which a new use has been discovered; this provision shall not apply to the use itself, where it constitutes an invention under Section 1;**
- (e) **Animals other than micro-organisms, and essentially biological processes for the production of animals and their parts, other than non-biological and microbiological processes;**
- (f) **Inventions, the prevention within the territory of Oman of the commercial exploitation of which is necessary to protect *ordure public* and morality; such exclusion shall not be made merely because the exploitation of those inventions is prohibited by law.**

(2) The provisions of subsection (1) shall not apply to the following inventions:

- (a) **Process inventions which, in whole or in part, consist of steps that are performed by a computer and are directed by a computer program; and**
- (b) **Product inventions consisting of elements of a computer-implemented invention, including in particular:**
 - (i) **Machine-readable computer program code stored on a tangible medium such as a floppy disk, computer hard drive or computer memory; and**
 - (ii) **a general purpose computer whose novelty over the prior art arises primarily due to its combination with a specific computer program.**

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?

Section 13

(1) (a) Where

- (i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or**
- (ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice; or**
- (iii) the owner of the patent is abusively exercising his exclusive rights and/or neglecting in taking measures to prevent his licensee(s) from abusively exercising the licensed exclusive rights; or**
- (iv) the invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation; or**
- (v) when a patent (the “second patent”) claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the “first patent”) without infringing which the second patent cannot be exploited.**

(2) A compulsory license may not be applied for on the ground of insufficient availability of the patented product or of the product manufactured with the patented process, as established in subsection (1)(a)(iv), before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last; it shall be refused if the patentee justifies his inaction or insufficient action by legitimate reasons.

(3) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(4) (a) Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

(b) Notwithstanding paragraph (a), the Minister shall not terminate the compulsory license if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision or, if the compulsory license was granted to remedy an anti-competitive practice under subsection (1)(a)(ii), if and when the conditions which led to such compulsory license are likely to recur.

(5) The compulsory license may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(6) The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:

- (i) the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and**
- (ii) the conclusion of license contracts by the owner of the patent; and**
- (ii) the continued exercise, by the owner of the patent, of his rights under Section 11(1), (2) and (3).**

(7) (a) A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.

(b) Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.

(8) The exploitation of the invention by the Government agency or third person licensed by the Minister shall be predominantly for the supply of the market in Oman except when the compulsory license concerns a patent claiming a pharmaceutical product or a process of making a pharmaceutical product, and the purpose of the license is to export the patented products or the products manufactured by the patented process for a foreign territory or country with no or with insufficient manufacturing capacity, in accordance with the terms and conditions of the Decision of the General Council of the WTO of August 30, 2003.

(9) Compulsory licenses of inventions in the field of semi-conductor technology shall only be granted for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented inventions, by the owner of the patents or his licensees, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.

(10) Where a compulsory license is granted under subsection (1)(v),

(a) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(b) the license of the first patent shall be non-assignable except with the assignment of the second patent.

(11) The provisions of this Section shall apply, where appropriate and *mutatis mutandis*, to pending patent applications, except in the case of insufficient availability of the patented product or of the product manufactured with the patented process.

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.).

Section II: Private and/or non-commercial use

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

Industrial Property Law 67/2008 - Section 11 -(4) (b) (i)

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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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).

(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):

Industrial Property Law 67/2008 - Section 11 -(4) (a) (iii).....

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

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

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

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

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:

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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):

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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:

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):

... The rights under the patent shall not extend: to acts done only for experimental purposes relating to a patented invention

Section 11

(4) (a) The rights under the patent shall not extend:

(i) to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or

(ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or

- (iii) to acts done only for experimental purposes relating to a patented invention;
or
- (iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the “prior user”);

(v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman.

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):

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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):

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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:

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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:

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Section IV: Preparation of medicines

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

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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:

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):

Industrial Property Law 67/2008 - Section 11 -(4) (a) (iv).....

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

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33. (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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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):

Section 11

(4) (a) The rights under the patent shall not extend:

- (i) to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or**
- (ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or**
- (iii) to acts done only for experimental purposes relating to a patented invention; or**
- (iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the "prior user");**
- (v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman.**

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

Section 13

(B) The Minister may - without the consent of the owner of the patent - to decide that any governmental entity or other person exploiting the invention, and this exploitation is limited to the purpose for which licenses it for, to pay adequate compensation to the owner of the patent depending on the circumstances of each case, taking into account the value Economic Minister's decision, and the provisions of the General Council Decision of the WTO that it was appropriate for the reward, which was decided at the grant of a patent for the invention of the mandatory drug product or an industrial process for the manufacture of this product.

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

X 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?

X Yes
No

If yes, please explain what those conditions are:

Section 11

(4) (a) The rights under the patent shall not extend:

- (i) to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or**
- (ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or**
- (iii) to acts done only for experimental purposes relating to a patented invention; or**
- (iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the "prior user");**

(v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman

(6) The right of the prior user referred to in subsection (4)(a)(iv) of this Section may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made.

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:

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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):

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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:

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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:

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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):

Industrial Property Law 67/2008 - Section 11 -(4) (b) (ii).....

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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:

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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

- 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):

the applicable law is silent on those issues

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):

the applicable law is silent on those issues

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):

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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:

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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:

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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):

Industrial Property Law 67/2008 - Section 13.....
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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:

(1) (a) Where

- (i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or**
- (ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice; or**
- (iii) the owner of the patent is abusively exercising his exclusive rights and/or neglecting in taking measures to prevent his licensee(s) from abusively exercising the licensed exclusive rights; or**
- (iv) the invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation; or**
- (v) when a patent (the “second patent”) claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the “first patent”) without infringing which the second patent cannot be exploited.**

(2) A compulsory license may not be applied for on the ground of insufficient availability of the patented product or of the product manufactured with the patented process, as established in subsection (1)(a)(iv), before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last; it shall be refused if the patentee justifies his inaction or insufficient action by legitimate reasons.

(3) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(4) (a) Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

(b) Notwithstanding paragraph (a), the Minister shall not terminate the compulsory license if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision or, if the compulsory license was granted to remedy an anti-competitive practice under subsection (1)(a)(ii), if and when the conditions which led to such compulsory license are likely to recur.

(5) The compulsory license may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(6) The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:

- (i) the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and**
- (ii) the conclusion of license contracts by the owner of the patent; and**
- (ii) the continued exercise, by the owner of the patent, of his rights under Section 11(1), (2) and (3).**

(7) (a) A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.

(b) Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.

(8) The exploitation of the invention by the Government agency or third person licensed by the Minister shall be predominantly for the supply of the market in Oman except when the compulsory license concerns a patent claiming a

pharmaceutical product or a process of making a pharmaceutical product, and the purpose of the license is to export the patented products or the products manufactured by the patented process for a foreign territory or country with no or with insufficient manufacturing capacity, in accordance with the terms and conditions of the Decision of the General Council of the WTO of August 30, 2003.

(9) Compulsory licenses of inventions in the field of semi-conductor technology shall only be granted for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented inventions, by the owner of the patents or his licensees, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.

(10) Where a compulsory license is granted under subsection (1)(v),

(a) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(b) the license of the first patent shall be non-assignable except with the assignment of the second patent.

(11) The provisions of this Section shall apply, where appropriate and *mutatis mutandis*, to pending patent applications, except in the case of insufficient availability of the patented product or of the product manufactured with the patented process.

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: **Exploitation**

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):

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):

Industrial Property Law 67/2008 - Section 13.....

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:

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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):

Section 13

(6) The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:

- (i) the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and**
- (ii) the conclusion of license contracts by the owner of the patent; and**
- (ii) the continued exercise, by the owner of the patent, of his rights under Section 11(1), (2) and (3).**

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

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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:

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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):

Industrial Property Law 67/2008 - Section 13.....
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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:

68. (a) What are the public policy objectives for providing compulsory licenses in your country? 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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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 invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation

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):

Section 11

(5) Without prejudice to the provisions of subsection 4(a) of this Section, the Minister shall have the authority, ex officio or at the request of any interested party, of declaring the patent rights exhausted, and thus of authorizing others to import the patented product or a product manufactured directly or indirectly by means of the patented invention (“the product”) from another territory when that product is not available in the territory of Oman or is available in the territory of Oman with unreasonably low quality standards or in a quantity that is not sufficient to meet the

local demand or at prices that the Minister deems abusive or for any other reason of public interest, including anticompetitive practices, provided that:

- (i) the product has been put in the channels of commerce in the territory from which it will be imported by the owner of the patent or with his consent; and
- (ii) a patent claiming the product or the process for its manufacture is in force in the territory from which the product will be imported and is owned by the same person who owns the patent in Oman or by a person under his control:

(a) If the importer fails to fulfill the purpose that justified the Minister's decision to consider the patent rights exhausted, the Minister shall, ex officio, or at the request of the patent owner, cancel the authorization.

(b) If the conditions that gave rise to the Minister's decision to consider the patent exhausted cease to exist, the Minister may, ex officio or at the request of the patent owner, cancel the authorization, provided that the legitimate interests of the importer are taken into account, including but not exclusively that the importer will retain the right to commercialize the products that remain on stock.

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? **four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last**

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"? **Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that**

the Government agency or third person designated by him has failed to comply with the terms of the decision

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):

A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time

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):

TITLE III: PROTECTION AGAINST UNFAIR COMPETITION

Section 60

(1) The provisions of this Title shall apply independently of, and in addition to, any legislative provisions protecting inventions, utility models, industrial designs, layout-designs, distinctive signs, literary and artistic works and other intellectual property subject matter.

(2) (a) In addition to the acts and practices referred to in Articles 61 to 65, any act or practice, in the course of industrial or commercial activities, that is contrary to honest practices shall constitute an act of unfair competition.

(b) An act or practice that is contrary to honest practices, for the purposes of this Title, shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

An act or practice that is contrary to honest practices, for the purposes of this Title, shall also mean acts of breach of legal duties in general when their purpose or their consequence is to obtain illicit advantages over competitors, such as the breach of environmental or labor law.

(c) Any natural person or legal entity damaged or likely to be damaged by an act of unfair competition shall be entitled to the remedies referred to in Title IV.

Section 61

(1) Any act or practice, in the course of industrial or commercial activities, that causes, or is likely to cause, confusion with respect to another's enterprise or its activities, in particular, the products or services offered by such enterprise, shall constitute an act of unfair competition.

(2) Confusion may, in particular, be caused with respect to

- (i) a trademark, whether registered or not or a trade name.
- (ii) any distinctive sign other than a trademark or a trade name
- (iii) ; the appearance of a product or the presentation of products or services as well as of the place of business]

Section 62

(1) Any act or practice, in the course of industrial or commercial activities, that damages, or is likely to damage, the goodwill or reputation of another's enterprise shall constitute an act of unfair competition, regardless of whether such act or practice causes confusion.

(2) (a) Damaging another's goodwill or reputation may, in particular, result from the dilution of the goodwill or reputation attached to

- (i) a trademark, whether registered or not;
- (ii) a trade name;
- (iii) any distinctive sign other than a trademark or a trade name;
- (iv) the appearance of a product;
- (v) the presentation of products or services as well as of the place of business;
- (vi) a celebrity or a well-known fictional character.

(b) For the purposes of these provisions, "dilution of goodwill or reputation" means the lessening of the distinctive character or advertising value of a trademark, trade name or other business identifier, the appearance of a product or the presentation of products or services or of a celebrity or well-known fictional character.

Section 63

(1) Any act or practice, in the course of industrial or commercial activities, that misleads, or is likely to mislead, the public with respect to an enterprise or its activities, in particular, the products or services offered by such enterprise, shall constitute an act of unfair competition.

(2) Misleading may arise out of advertising or promotion and may, in particular, occur with respect to

- (i) the manufacturing process of a product;
- (ii) the suitability of a product or service for a particular purpose;
- (iii) the quality or quantity or other characteristics of products or services;
- (iv) the geographical origin of products or services;
- (v) the conditions on which products or services are offered or provided;
- (vi) the price of products or services or the manner in which it is calculated.

Section 64

(1) Any false or unjustifiable allegation, in the course of industrial or commercial activities, that discredits, or is likely to discredit, another's enterprise or its activities, in particular, the products or services offered by such enterprise, shall constitute an act of unfair competition.

(2) Discrediting may arise out of advertising or promotion and may, in particular, occur with respect to

- (i) the manufacturing process of a product;
- (ii) the suitability of a product or service for a particular purpose;
- (iii) the quality or quantity or other characteristics of products or services;
- (iv) the conditions on which products or services are offered or provided;
- (v) the price of products or services or the manner in which it is calculated.

Section 65

(1) Any act or practice, in the course of industrial or commercial activities, that results in the disclosure, acquisition or use by others of undisclosed information without the consent of the person lawfully in control of that information (hereinafter referred to as “the rightful holder”) and in a manner contrary to honest commercial practices shall constitute an act of unfair competition.

For the purposes of this Section, “a manner contrary to honest commercial practices” shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

(2) For the purposes of this Section, information shall be considered “undisclosed information” if it has secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question or it has commercial value because it is secret and it has been subject to reasonable steps under the circumstances by the person lawfully in control of the information to keep it secret.

(3) (a) Any act or practice, in the course of industrial or commercial activities, shall be considered an act of unfair competition if it consists or results in

- (i) an unfair commercial use by a governmental authority of undisclosed test or other data concerning safety and efficacy of the product which have been submitted to that authority as a condition of obtaining approval of the marketing of new pharmaceutical or agricultural chemical products, or
- (ii) the disclosure of such data, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

(b) For the purposes of this Subsection, a pharmaceutical product shall be considered new if it contains a chemical entity that has not been previously approved in the territory of Oman for use in a pharmaceutical product; a new agricultural chemical shall be considered new if it contains a chemical entity that has not been previously approved in the territory of Oman for use in an agricultural chemical product.

(4) (a) Subsection (4)(a)(i) shall be construed as precluding any governmental agency, without the consent of the person or entity who first obtained marketing approval of a pharmaceutical or agricultural chemical product in Oman (the originator) from relying on or

referring to the undisclosed test data or other undisclosed data submitted by the originator, for the purposes of approving any other product, for at least five (5) years for pharmaceutical products, and ten (10) years for agricultural chemical products, from the date of marketing approval in Oman

(b) The provisions of paragraph (a) of this Subsection shall apply, *mutatis mutandis*, in the event Oman adopts the practice of granting marketing approval based on evidence of marketing approval granted in another territory.

(c) Where the competent authority of Oman requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of a pharmaceutical product, other than information related to bioequivalency, that competent authority shall not, without the consent of the originator, authorize another to market a same or a similar product based on the new clinical information submitted in support of the marketing approval or evidence of the marketing approval based on the new clinical information, for at least three years from the date of marketing approval in Oman.

(d) The provisions of paragraph (c) of this Subsection shall apply, *mutatis mutandis*, in the event Oman adopts the practice of granting marketing approval based on evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory.

(e) Where the originator's product is covered by a patent in force in the territory of Oman, the competent authority, notwithstanding the provisions of this Subsection, but without prejudice to the provisions of paragraph (e), shall not approve another product without the prior consent of the patent owner. If a request of marketing approval that requires or implies reliance on the originator's undisclosed data is submitted by another person during the term of a patent, the competent authority shall inform the patent owner of such a request

Section 13

(7) (a) A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.

(b) Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive,

provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.

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:

.. when a patent (the “second patent”) claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the “first patent”) without infringing which the second patent cannot be exploited

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:

Section 13

(B) The Minister may - without the consent of the owner of the patent - to decide that any governmental entity or other person exploiting the invention, and this exploitation is limited to the purpose for which licenses it for, to pay adequate compensation to the owner of the patent depending on the circumstances of each case, taking into account the value Economic Minister's decision, and the provisions of the General Council Decision of the WTO that it was appropriate for the reward, which was decided at the grant of a patent for the invention of the mandatory drug product or an industrial process for the manufacture of this product.

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 applicable law is silent on those issues

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

Neither a compulsory license nor a government use license has ever been issued in the Sultanate of Oman

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:

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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:

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Government use

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

Industrial Property Law 67/2008 - Section 11-4e and Section 13.....

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:

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

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(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 applicable law is silent on those issues

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

Neither a compulsory license nor a government use license has ever been issued in the Sultanate of Oman

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:

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

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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):

Industrial Property Law 67/2008 - Section 11 – 4 to 6.....

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):

Section 11

(4) (a) The rights under the patent shall not extend:

(i) to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or

- (ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or
- (iii) to acts done only for experimental purposes relating to a patented invention; or
- (iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the “prior user”);

(v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman

(6) The right of the prior user referred to in subsection (4)(a)(iv) of this Section may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made.

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):

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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:

**Industrial Property Law 67/2008 - Section 66
Infringement Proceedings**

(6) (a) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement of a patent for a diagnostic, therapeutic and surgical methods for the treatment of humans or animals, the provisions of Title IV of this Act shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

(b) For the purposes of this Subsection:

- (i) the term “medical activity” means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent;
- (ii) the term “medical practitioner” means any natural person who is licensed by a State to provide the medical activity described in paragraph (b)(1) or who is acting under the direction of such person in the performance of the medical activity;
- (iii) the term “related health care entity” shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic;

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):

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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:

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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?):

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

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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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[End of Questionnaire]