

## Section 1: General

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

*Section 22 of the Industrial Property Act, 2002 (IPA) which provides that:*

*“An invention is patentable if it is new, involves an inventive step, is industrially applicable or is a new use”*

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.<sup>1</sup>

*Section 21(3) of the IPA excludes the following from patent protection*

- (a) Discoveries, scientific theories and mathematical methods;*
- (b) Schemes, rules or methods for doing business, performing purely mental acts or playing games;*
- (c) Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced in relation thereto, except products for use in any such methods;*
- (d) Mere presentation of information; and*
- (e) Public health related methods of use or uses of any molecule or other substance whatsoever used for the prevention or treatment of any disease, which the minister responsible for matters relating to health may designate as a serious health hazard or as a life threatening disease.*

*Section 26 also excludes the following from patent protection:*

- (a) Plant varieties (which are protected by another law)*
- (b) Inventions contrary to public order, morality, public health and safety, principles of humanity and environmental conservation.*

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 54: rights of owner of patent*

*54. (1) The owner of the patent shall have the right to preclude any person from exploiting the protected invention by any of the following acts –*

- (a) when the patent has been granted in respect of a product -*
  - (i) making, importing, offering for sale, selling and using the product; or*
  - (ii) stocking such product for the purposes of offering it for sale, selling or using the product;*
- (b) when the patent has been granted in respect of a process -*
  - (i) using the process, or*
  - (ii) doing any of the acts referred to in paragraph (a), in respect of a product obtained directly by means of the process.*

*Section 55: Enforcement of rights*

*55. The owner of a patent shall have the right -*

- (a) to obtain an injunction to restrain the performance or the likely performance, by any person without his authorization, of any of the acts referred to in section 54; and*
- (b) to claim damages from any person who, having knowledge of the patent, performed any of the acts referred to in section 54, without the owner's authorization.*

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

*(c) to claim compensation from any person who, without his authorization, performed any of the inventions, claimed in the published application, as if a patent had been granted for that invention: Provided that the said person, at the time of the performance of the act, had -*  
*(i) actual knowledge that the invention that he was using was the subject matter of a published application; or*  
*(ii) received written notice that the invention that he was using was the subject matter of a published application, such application being identified in the said notice by its serial number.*

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

*Non-commercial use; (section 58(1))*

*Scientific research; (section 58(1))*

*Prior use; (section 56(1))*

*Use of articles on foreign vessels, aircrafts and land vehicles; (section 58(3))*

*Acts for obtaining regulatory approval from authorities; (section 54(2))*

*Exhaustion of patent rights; (section 58(2))*

*Compulsory licensing; Section 72-78*

*Government use; (section 80)*

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 2: Private and/or non-commercial use**

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

*Section 58: Limitation of rights*

*(1) The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research.*

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

*[Note from the Secretariat: response was not provided]*

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

*To allow research during the term of the patent.*

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

*See the answer to question 68*

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

*The IPA does not provide a definition*

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):

*[Note from the Secretariat: response was not provided]*

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:

*There are no planned amendments*

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

*None*

### **Section 3: Experimental use and / or scientific research <sup>2</sup>**

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

*The answer is as provided under section II above*

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

*The answer is as provided under section II above*

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

*The answer is as provided under section II above*

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

*See the answer to question 68*

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

*No*

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

*The IPA does not provide a definition*

16.-20.

*[Note from the Secretariat: response was not provided]*

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<sup>2</sup> Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

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 planned amendments*

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

*[Note from the Secretariat: response was not provided]*

#### **Section 4: Preparation of medicines**

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

*The IPA does not provide exceptions related to the preparation of medicines*

24.-30.

*[Note from the Secretariat: response was not provided]*

#### **Section 5: Prior use**

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

*Section 56: Right of a prior user*

*(1) Notwithstanding the provisions of section 54, a patent shall have no effect against any person (hereinafter referred to as "the prior user") who, in good faith, for the purposes of his enterprise or business, before the filing date or, where priority is claimed, the priority date of the application on which the patent is granted, and within the territory where the patent produces its effect, was using the invention or was making effective and serious preparations for such use; any such person shall have the right, for the purposes of his enterprise or business, to continue such use or to use the invention as envisaged in such preparations.*

*(2) The right of the prior user may only be transferred or devolve together with his enterprise or business, or with that part of his enterprise or business in which the use or preparations for use have been made.*

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

*[Note from the Secretariat: response was not provided]*

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

*Section 23 (4) of the IPA provides a grace period for disclosure of the invention by the applicant predecessor in title before a patent application is filed. The prior use exception is a balancing provision such that a person who exploits the invention based on the disclosure is free to exploit the invention even after the grant of a patent.*

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

*See the answer to question 68*

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):

*The IPA does not provide a definition or limitation*

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

*No*

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

*Yes, the right of the prior user may only be transferred to a third party together with his enterprise or business.*

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?

*No*

If yes, please explain what those conditions are:

*The right of the prior user may only be transferred together with his enterprise or business, or with that part of his 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

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

*Section 61: Annual fees*

*(7) Where a patent is restored, no proceedings shall be brought in respect of the patent.*

*(a) with respect to any acts performed after the lapse of the patent and before the date of the order for restoration; or*

*(b) with respect to any acts performed after the date of the order of restoration in relation to articles imported into or manufactured in Kenya, after the lapse of the patent and before the date of the order for restoration.*

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

*No other criteria is provided for*

40.-41.

*[Note from the Secretariat: response was not provided]*

## **Section 6: Use of articles on foreign vessels, aircrafts and land vehicles**

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

*Section 58*

*(3) The rights under the patent shall not extend 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 Kenya.*

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

*[Note from the Secretariat: response was not provided]*

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

*[Note from the Secretariat: response was not provided]*

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

*See the answer to question 68*

45. The exception applies in relation to:

*Vessels  
Aircrafts  
Land Vehicles*

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

*These terms are included in section 58(3). However, they are not defined.*

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):

*Section 58(3) refer to "use of articles on aircraft"*

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):

*[Note from the Secretariat: response was not provided]*

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:

*There are no planned amendments.*

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

*[Note from the Secretariat: response was not provided]*

## **Section 7: Acts for obtaining regulatory approval from authorities**

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

*Section 54(2)*

*The rights conferred on the owner of the patent under this section shall not apply to acts by third parties necessary to obtain approval or registration of a product from the Institute for the purpose of commercializing the product after expiry of the patent.*

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

*[Note from the Secretariat: response was not provided]*

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

*To allow other manufacturers to seek regulatory approval before a patent expires so that they can market the product as soon as the patent expires. In addition see the answer to question 68 below*

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

*[Note from the Secretariat: response was not provided]*

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

*There are no restrictions as to who may use the exception*

55. The exception covers the regulatory approval of:

*A product*

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

*Acts by third parties necessary to obtain approval or registration of a product*

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

*[Note from the Secretariat: response was not provided]*

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:

*A proposal was submitted to amend Section 54(2) by deleting the words "the Institute" and substituting thereof the words "a relevant authority". According to the IPA, Institute means Kenya Industrial Property Institute (KIPI). However, KIPI does not give marketing approval. This is done by other authorities such as the Pharmacy and Poisons Board in case of pharmaceutical products or the Pest Control Board in case of pesticides.*

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

*[Note from the Secretariat: response was not provided]*

## **Section 8: Exhaustion of patent rights**

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

*National and International*

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

*Section 58 (2) of IPA provides that*

*The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.*

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

*See the answer to question 68*

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

*To allow parallel importation of patented products thus balancing between the interests of patentees and consumers*

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

*See the answer to question 68*

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?

*No*

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

*[Note from the Secretariat: response was not provided]*

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

*Yes*

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

*The issue of exhaustion of rights and parallel importation was considered by the Industrial Property Tribunal in the case of Pfizer Inc. v Cosmos Limited (IPT Case 49 of 2006) in which the respondent, who was accused of infringement, contended that section 58(2) allowed it to import, sell, manufacture or otherwise deal with patented products without the authority of the patent holder. The Tribunal however clarified that section 58(2) "was meant to protect acts done by third parties who are not the patent holder but who are allowed to deal with the patented products in any of the exceptions or flexibilities" such as parallel importation.*

## **Section 9: Compulsory licenses and/or government use**

Compulsory licenses

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

*Section 72. Compulsory licences for nonworking and similar reasons*



(1) At any time after four years from the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may apply to the Tribunal for a licence to exploit the patented invention on the grounds that a market for the patented invention is not being supplied on reasonable terms in Kenya.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be granted if the owner of the patent satisfies the Tribunal that circumstances exist which justify the fact that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Kenya.

*Section 73: Compulsory licences based upon interdependence of patents.*

(1) Where a patented invention cannot be worked without infringing the rights derived from an earlier patent, the owner of the latter patent may request the Tribunal at any time for the grant of a compulsory licence with respect to the earlier patent to the extent necessary for the working of his invention, if the invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent.

(2) The owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent.

(3) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

(4) In this section, "earlier patent" or "first patent" means a patent granted on an earlier application or benefiting from an earlier validly claimed priority date, and "latter patent" or "second patent" shall be construed accordingly.

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

*[Note from the Secretariat: response was not provided]*

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

*Non-working or insufficient working of the patented invention*

*Refusal to grant licenses on reasonable terms*

*Anti-competitive practices and/or unfair competition*

*Public health*

*National emergency and/or extreme urgency*

*Dependent patents*

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

*To ensure a balance between the rights of the patentee and the public interest*

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

*In Pfizer Inc. v Cosmos Limited (IPT Case 49 of 2006), the Industrial Property tribunal ruled that the provisions (on exceptions) in the IPA are to "balance between the rights of the patent holders vis-à-vis those of the public and third parties".*

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 IPA does not define these terms and they would be decided on a case by case. Further, a definition of the said terms would have arisen where an application for grant of a compulsory licence had been made before the Industrial Property Tribunal. Unfortunately, no such application has been made before the Tribunal.*

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 section 54 of the IPA, the patentee has exclusive rights to exploit their invention, for example by importation of the product. Importation of a product obtained directly by means of a patented process would constitute infringement.*

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

Yes

If yes, what is the time period?

*At any time after 4 years from the filing date of an application or 3 years from date of the grant of a patent, whichever period last expires.*

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

If yes, what are “legitimate reasons”?

*There are specified in the law*

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):

*These terms are used in the law. However they are not defined and would be determined on a case by case basis*

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):

*Anti-competitive practices are covered under the provisions of government use. See the answer to question 83.*

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:

*Section 73(1) of the IPA provides that where a patented invention cannot be worked without infringing the rights derived from an earlier patent, the owner of the latter patent may request the Tribunal at any time for the grant of a compulsory licence with respect to the earlier patent to the extent necessary for the working of his invention, if the invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent.*

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

*Section 75 of the IPA provides for the payment of equitable remuneration to the patentee, with due regard to all the circumstances of the case, including the economic value of the licence.*

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

*These concepts are not used in the IPA.*

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

*None so far*

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:

*There are no planned amendments*

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

*Government use*

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

*Section 80 of the IPA which provides that*

*(1) Where*

*(a) the public interest, in particular, national security, nutrition, health, environmental conservation, or the development of other vital sector of the national economy so requires: or*

*(b) the Managing Director determines that the manner of exploitation of an invention by the owner of the patent or his licensee is not competitive; the Minister may, upon application to him in the prescribed form and after consultation with the Institute and the owner of the patent, order that the protected invention shall be exploited by a Government Ministry, Department, agency or other person as the Minister may designate in the order, subject to the payment of adequate compensation to the owner of the patent in accordance with this section.*

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

*[Note from the Secretariat: response was not provided]*

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

*Anti-competitive practices and/or unfair competition*

*Public health*

*National security*

*National emergency and/or extreme urgency*

*Public interest (national security, nutrition, health, environmental conservation, or the development of other vital sector of the national economy)*

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

*Public/National interest/development of national economy*

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

*Section 80 of the IPA as indicated in question 81*

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

*These concepts are not used in the IPA in relation to government use provisions.*

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

*None so far, though an application for government use order with respect to pharmaceutical products was made in 2004 but the parties negotiated and agreed on a voluntary licence.*

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:

*There are no proposed amendments*

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

*[Note from the Secretariat: response was not provided]*

## **Section 10: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions**

*Farmers’ use of patented inventions*

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

*There are no provisions in the IPA regarding this subject matter.*

90.-93.

*[Note from the Secretariat: response was not provided]*

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

*Breeders’ use of patented inventions*

95.-100.

*[Note from the Secretariat: response was not provided]*

## **Section 11: Other Exceptions and Limitations**

101.-102.

*[Note from the Secretariat: response was not provided]*

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:

*Section 21 of the Competition Act 2010 prohibits agreements, practices and decisions, which have the effect of preventing, distorting or lessening competition in trade in any goods or services in Kenya. The prohibition applies to any agreement, decision or concerted practice, which amounts to use of an intellectual property right in a manner that goes beyond the limits of legal protection.*

*Section 24 of the same Law also prohibits conducts, which may amount to abuse of a dominant market position, including abuse of an intellectual property right.*