

## Intellectual Property Corporation of Malaysia

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### 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.

*An invention is patentable if it is new, involves an inventive step and industrially applicable, as mentioned in Section 11 of the Patents Act.*

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.

*List of exclusions from patentability as stipulated in Section 13 of the Patents Act, are as follows:*

- (a) discoveries, scientific theories and mathematical methods;*
- (b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;*
- (c) schemes, rules or methods for doing business, performing purely mental acts or playing games;*
- (d) methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body.*

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?

*The exclusive rights granted with a patent as mentioned in Section 36 of the Patents Act, are as follows:*

- (a) to exploit the patented invention;*
- (b) to assign or transmit the patent;*
- (c) to conclude license contracts*

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;*  
*Prior use;*  
*Use of articles on foreign vessels, aircrafts and land vehicles;*  
*Acts for obtaining regulatory approval from authorities;*  
*Compulsory licensing and/or government use.*

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

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

*Section 37 of the Patents Act*

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

*None*

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

*To promote technological innovation and to dissemination of technology*

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

*None*

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):

*None*

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

*No*

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:

*Yes*

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

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

*Section 37 of the Patents Act*

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

None

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

*To encourage scientific research and technological progress and to promote inventive activities.*

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

None

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):

No

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*

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”)*

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

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

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*

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):

*None*

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):

*None*

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:

*Yes*

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

*None*

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

23.-30.

*N/A*

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

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

*Section 38 of the Patents Act.*

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

*None*

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

*It is intended to safeguard the rights of third parties who have independently used an invention before the priority date of an application for a patent*

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

*None*

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):

*No*

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?

*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?

*No*

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

*No*

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):

*None*

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:

*Yes*

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

*None*

## **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 37 of the Patents Act*

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

*None*

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

*To facilitate the free transit (temporarily) of international means of transportation without being in force the existence of patent rights*

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

*None*

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 apply such terms as "temporarily"*

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):

*None*

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):

*None*

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:

*Yes*

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

*None*

## **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 37 of the Patents Act*

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

*None*

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

*Since the processes would take some time, this exception could gain the regulatory approval just after the term has expired.*

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

*None*

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

*No restrictions as to who may use the exception*

55. The exception covers the regulatory approval of:

*Any products*

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

*Making*

*Using*

*Selling*

*Offering for sale*

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):

*None*

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:

*Yes*

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

*None*

**Section 8: Exhaustion of patent rights**

60.-64.

*N/A*

## 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):

*Part X (Section 48 – 54) of the Patents Act*

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

*None*

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*

*Dependent patents*

*Sold at unreasonably high prices or not meet the public demand*

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

*To ensure the balance between the patent monopoly and the public interest*

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

*None*

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):

*If the patentee fails to exploit the patent without any legitimate reason*

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*

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?

*After 3 years from the grant of a patent, or 4 years from the filing date of the patent application*



72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

*Determine on a case-by-case basis*

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):

*None*

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):

Yes

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 49A provides with circumstances where the patented invention cannot be worked without infringing another 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 52(c) provides such a general rule*

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:

*None*

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

*None*

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:

Yes

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

*None*

*Government use*

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

*Section 84 of the Patents Act*

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

*No*

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*

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

*To allow the government to use the patented inventions particularly in relation to national emergency, national security, health or public interest*

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

*None*

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:

*None*

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

*Only once, on pharmaceutical products*

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:

*Yes*

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

*None*

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

*Farmers' use of patented inventions*

89.-100.

N/A

**Section 11: Other Exceptions and Limitations**

101.-103.

N/A

[End of Questionnaire]