Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: The Netherlands (and Curaçao and St. Maarten)
Office: Netherlands Patent Office (NL Octrooicentrum)

Person to be contacted:

Name: Feike Liefrink
Title: Manager Patent Unit
E-mail: feike.liefrink@agentschapnl.nl
Telephone: +31 88 602 6342
Facsimile: +31 88 602 0898

or

Name: Jeroen Meewisse
Title: Examiner
E-mail: jeroen.meewisse@agentschapnl.nl
Telephone: +31 88 602 6357
Facsimile: +31 88 602 0898

In the questionnaire references are made to the Netherlands patent act and the parliamentary papers. The official text of the Netherlands patent act and the parliamentary papers can be found on the website of the Netherlands Patent Office:
- Netherlands Patent Act 1995: www.agentschapnl.nl/onderwerp/wet-en-regelgeving-octrooien;
- Parliamentary papers: www.agentschapnl.nl/onderwerp/wetsgeschiedenis-octrooien.

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.

   According to art. 2(1) of the Netherlands Patent Act of 1995 (hereinafter referred to as: NPA 1995) inventions that are new, that involve an inventive step and that are susceptible of industrial application shall be patentable. In addition to art. 2(1) NPA 1995,

art. 2a NPA 1995 contains a specific provision for inventions relating to biological material.

Novelty is defined in art. 4 NPA 1995, inventive step in art. 6 NPA 1995 and susceptibility of industrial application in art. 7 NPA 1995.

In principle, the above mentioned requirements are interpreted according to the guidelines and the case law of the European Patent Office under the provisions of the European Patent Convention. See for example a recent decision of the District Court The Hague (*BIE* 2011/5, Sandoz/Glaxo).

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]

According to art. 2(1) NPA 1995, the following subject matter or activities are excluded from patentability, because of not being regarded as inventions in the meaning of art. 2(1) NPA 1995:
a. discoveries, as well as scientific theories and mathematical methods;
b. aesthetic creations;
c. schemes, rules and methods for performing mental acts, playing games or doing business, as well as computer programs; and
d. presentations of information,
but only insofar as it concerns the subject matter or activities referred to as such.

According to art. 3(1) NPA 1995, the following inventions are not patentable:
a. inventions whose commercial exploitation would be contrary to the public order or public morality;
b. the human body in its various stages of its formation and its development, as well as the sole discovery of one of its parts, including a sequence or partial sequence of a gene;
c. plant or animal varieties;
d. essentially biological processes consisting entirely of natural phenomena such as hybridisations or selections in order to produce plants or animals and the products obtained thereby;
e. inventions that lead to an infringement of Articles 3, 8(j), 15(5) and 16(5) of the Convention on Biological Diversity; or
f. methods of treating the human or animal body by means of surgery or medical treatment and diagnostic methods that are applied to the human or animal body, with the exception of products, in particular substances or compositions, for the application of such methods.

Art. 3(2) NPA 1995 specifies that inventions whose commercial exploitation would be contrary to the public order or public morality within the meaning of article 3(1)(a) in any event include:
a. methods to clone human beings;
b. methods to change the germinal genetic identity of human beings;
c. the use of human embryos;
d. methods to change the genetic identity of animals that would lead to those animals suffering without that yielding considerable medical benefit for human beings or animals, as well as the products acquired thereby; and

---

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

e. methods that endanger the life or the health of human beings, animals or plants or that cause serious damage to the environment.

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?

Rights according to a national patent application
According to art. 71(1) NPA 1995, the patent holder may, under certain conditions, demand reasonable compensation from any party who has performed acts as referred to in art. 53(1) NPA 1995 in the period between the registration (= publication) of the application that has led to the patent and the grant of the patent on that application or a divisional application, insofar as the patent holder has been granted exclusive rights in respect of such acts.
According to art. 71(2) NPA 1995, the patent holder may also demand reasonable compensation from any party who, after the grant of the patent as referred to in art. 71(1) NPA 1995, has performed the acts referred to in that provision with regard to products that were put on the market during the period stipulated in that paragraph. The patent holder may demand the same compensation from any party who, after the grant of the patent, has used for the purposes of his business products as specified in art. 53(1)(a) or (b) or art. 53a NPA 1995 that were manufactured in his business in the period referred to in art. 71(1) NPA 1995.
The compensation referred to in art. 71(1) and 71(2) shall be due only in respect of acts that are performed after the expiry of 30 days following the date on which the party concerned was notified, by means of a bailiff's writ indicating precisely which part of the patent application relates to such acts, of the rights that vest in the patent holder by virtue of art. 71 NPA 1995.
The right that vests in the patent holder by virtue of art. 71 NPA 1995 shall not extend to acts performed by a party who is entitled to perform such acts by virtue of art. 55 NPA 1995 (i.e. prior use) or by agreement, nor shall it extend to acts related to products that were put on the market either prior to the registration of the patent application in question or thereafter by the applicant or a person entitled to do so as specified above.

Rights according to a European patent application
According to art. 72 NPA 1995, similar rights apply for European patent applications. The time period of art. 71(1) NPA 1995 is replaced by the period between the publication pursuant to art. 93 of the European Patent Convention of the application that has resulted in the grant of the patent and the publication, referred to in art. 97(4) of that Convention, of the notification of the grant of the European patent in respect of that application or in respect of a divisional application related thereto by virtue of art. 76 of that Convention.
Moreover, the bailiff's writ as referred to in art. 71(3) NPA 1995, shall be served together with a translation into Dutch of the claims as contained in the publication of the European patent application in accordance with art. 93 of the European Patent Convention.

Rights according to a granted (national or European) patent
The exclusive rights granted with a patent are listed in art. 53(1) NPA 1995:
1. Subject to the provisions contained in Articles 54 to 60, a patent shall confer on its owner the exclusive right:
a. to make, use, put on the market or resell, hire out or deliver the patented product, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes;
b. to use the patented process in or for his business or to use, put on the market, or resell, hire out or deliver the product obtained directly as a result of the use of the patented process, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes.

In addition to art. 53(1) NPA 1995, art. 53a NPA 1995 provides specific provisions for exclusive rights relating to biological material:
1. With respect to a patent for biological material that has acquired certain characteristics as a result of the invention, the exclusive right shall include any biological material that is produced from such material by means of propagation or multiplication in the same or in a differentiated form and that has the same characteristics.
2. With respect to a patent for a process intended to produce biological material that has acquired certain characteristics as a result of the invention, the exclusive right shall include biological material that has been produced directly by that process and any other biological material that is produced from such material by means of propagation or multiplication in the same or in a differentiated form and that has the same characteristics.
3. With respect to a patent for a product that consists of or that contains genetic information, the exclusive right shall include any material in which that product is incorporated and in which the genetic information is included and performs its function, without prejudice to the provisions contained in art. 3(1)(b) NPA 1995 (see question 1).

Patent holders may enforce their rights towards parties that infringe these rights directly (art. 70 NPA 1995) or indirectly (art. 73 NPA 1995).

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

X Private and/or non-commercial use;
X Experimental use and/or scientific research;
- Preparation of medicines;[2]
X Prior use;
X Use of articles on foreign vessels, aircrafts and land vehicles;
X Acts for obtaining regulatory approval from authorities;
X Exhaustion of patent rights;
X Compulsory licensing and/or government use;
X Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.[3]

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

---

[2] For example, extemporaneous preparation of prescribed medicines in pharmacies.

[3] For example, in some countries where patent rights extend to propagated or multiplicated material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do not constitute patent infringement. Similarly, in some countries, patent rights do not cover uses by breeders of patented biological material for the purpose of developing a new plant variety (see paragraphs 133 to 137 of document SCP/13/3).

Section II: Private and/or non-commercial use

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

Art. 53 NPA 1995. The exclusive rights listed in art. 53(1) NPA 1995 are limited to activities 'in or for his business'. This means that private and non-commercial use are not included in the exclusive rights.

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

Not applicable.

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

The objective of the patent act is to acknowledge the right of the inventor and to provide him, as a reward for his contribution to the state of the art, with an exclusive right to exploit the invention. Extending the exclusive rights to private and non-commercial activities, would not concord with the above mentioned objective.

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

According to the Parliamentary Papers 197, 1904-1905, no. 3

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 term 'in or for his business' is interpreted broadly, to include all kinds of professional activities, including universities and governmental/administrative activities.
For example: District Court Alkmaar, 2 December 1991, *BIE* 1992/12: activities disbanding a bankrupt company are included in the term 'in or for his business'.

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):

Not applicable.

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 amendments foreseen.

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

Not applicable.

Section III: Experimental use and/or scientific research [4]

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

According to art. 53(3) NPA 1995 the exclusive right shall not extend to acts solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process.

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

From the case law it follows that the research exemption has to be interpreted restrictively. For example:
Supreme Court, 18 December 1992, *BIE* 1993/81 (ICI/Medicopharma): Infringing activities may only be carried out under art. 53(3) NPA 1995 if justified by the aim of the research. Aims qualifying as justification are genuine scientific research on the invention and aims that follow from the objectives of the NPA, such as investigating whether the invention can be put into practice or investigating whether the invention can be improved (realising technical progress).
Supreme Court, 23 June 1995, *NJ* 1996, 463 or *BIE* 1995/33 (ARS/Organon): The research exception of art. 53(3) NPA 1995 is not meant for research for commercial purposes such as clinical trials, but is allowable in a commercial company. See also section VII of this questionnaire.

13. (a) What are the public policy objectives for providing the exception?
One of the general objectives of the NPA is to stimulate technical progress. This objective cannot be met if, at least, genuine scientific research on the patented invention would infringe patent rights.

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

The general objectives of the NPA were already formulated in the Parliamentary Papers 197, 1904-1905, no. 3. Although at that time no research exemption was implemented in the NPA, this exception developed in case law. According to the Parliamentary Papers 13209, 1974-1975, no. 3, in which the explicit inclusion of the research exception in the NPA was discussed, the exception should also apply to research aiming to determine whether or not it is profitable to obtain a license from the patent holder. Such research benefits the patent holder.

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:

There is no distinction. Research ‘in or for a business’ is part of the exception. However, activities infringing a patent only fall under the exception if it can be proven that this research is indeed scientific or that this research parallels the objectives of the NPA.

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):

---

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

With the introduction of the NPA of 1910, the research exception was implicit in the term 'in or for his business'. Art. 30(3) NPA 1910, the predecessor of art. 53(3) NPA 1995 was introduced in 1977. In the accompanying parliamentary papers research was explained to include scientific research, also in or for a business. Furthermore, the research exception was to include research of patented inventions by professional parties aiming to decide whether or not to obtain a license from the patent holder.

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:

X determine how the patented invention works
X determine the scope of the patented invention
X determine the validity of the claims
X seek an improvement to the patented invention
X invent around the patented invention
X other, please specify: genuine scientific research

Note: the above mentioned activities are only allowed as far as they serve the objectives of the NPA. The precise scope of the exception is unknown.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

X 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):

Art. 53(3) NPA 1995 concerns "research on the patented subject matter".

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
X Both of the above
The commercial intention of the experimentation and/or research is not relevant

With respect to commercial purpose: research on a patented invention for licensing purposes is allowed.

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):

The NPA does not make a distinction. According to case law, research on a patented invention for licensing purposes is allowed. Furthermore, also commercial organisations may benefit from the research exception. See question 12.

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:

No amendments are foreseen.

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

None.

Section IV*: *Preparation of medicines

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

This exception is not contained in statutory law. However, the pharmacy exception was part of the proposed art. 53(3) NPA in 1995 (Parliamentary Papers 22604, 1991-1992). Inclusion of the pharmacy exception was originally proposed in order to harmonize the NPA 1910 with the European community patent agreement (Parliamentary Papers 19131, 1984-1985, no. 3). The pharmacy exception was meant for the preparation of pharmaceuticals, by pharmacists, for direct use, on prescription, in individual cases. The exception never came into force, as it was on hold for entry into force of the community patent agreement.

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

There is one example of legal proceedings in which a party defended itself by citing the pharmacy exception, however the court did not consider the argument, as it ruled that the pharmacy had forfeit any possible rights to the exception by a contract (District Court The Hague, 22 March 2006, case no. 04-1670. Merck & Co / Steunpunt Apotheek magistrale bereidingen Mierlo Hout B.V.)

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

The proposal aimed for harmonization of the NPA with the Community Patent Agreement.

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

Parliamentary Papers 19131, 1984-1985, no. 3).

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

The proposed exception was meant for pharmacists.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes
X No

Note: this concerns the proposal, see above.

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):

Not applicable.

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:

See question 23: the exception never came into force.

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

Not applicable.

Section V: Prior use

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

According to art. 55(1) NPA 1995, any party who, in The Netherlands or Curaçao or Sint Maarten, has already manufactured or applied or commenced implementation of his intention to manufacture or apply, in or for his business, the subject matter of a patent application filed by another party on the filing date thereof or, if the applicant has a right of priority under art. 9(1) NPA 1995 or art. 87 of the European Patent Convention, on the filing date of the priority application, shall, notwithstanding the patent, continue to have the right to perform the acts referred to in art. 53(1) NPA 1995, that right being based on prior use, unless his knowledge was obtained from matter already made or applied by the applicant or from the applicant's descriptions, drawings or models.

According to art. 55(3) NPA 1995, a party who, in good faith, has already manufactured or applied or commenced implementation of his intention to manufacture or apply, in or for his business, the subject matter in respect of which a European patent has been granted to another party before the date on which a notification of a corrected translation has been entered in the patent register shall, notwithstanding the patent, continue to have the right to perform the acts referred to in art. 53(1) NPA 1995 insofar as such acts do not infringe the patent holder's exclusive right, which right in this case will be determined by the content of the claims in the patent specification and the description and drawings intended for the interpretation thereof contained in the earlier, defective translation into Dutch.

According to art. 53(6) NPA 1995, a product within the meaning of art. 53(1)(a) or (b) NPA 1995 that was manufactured in a business prior to the grant of a patent or, if a European patent is concerned, prior to the date of publication of the notification that the European patent has been granted in accordance with art. 97(3) of the European Patent Convention, may continue to be used on behalf of that business notwithstanding the patent.

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

Not applicable.

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

55(1) NPA 1995: whatever the reasons were for the prior user (as defined in art. 55(1) NPA 1995) to keep the invention secret (e.g. no interest in a patent, business strategy, etc.), it is considered unfair if the patent holder could maintain his rights against the prior user. Without a “prior use” provision applying for a patent would be a necessity instead of a free choice.

Art. 55(3) NPA 1995: with this provision art. 70(4) of the European Patent Convention has been implemented in the NPA.

Art. 53(6): it is considered unfair if a patent holder could prevent products already manufactured in a business prior to the grant of his patent, but not put on the market prior to the grant of the patent, being used on behalf of that business after the grant of the patent.

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

The exception of art. 55(1) NPA 1995 was already introduced in the NPA in 1910 (Parliamentary Papers 197, 1904-1905, no. 3).
The exception of art. 55(3) NPA 1995 was introduced in the NPA in 2003 (Parliamentary Papers 27193, 1999-2000, no. 3).
The exception of art. 53(6) NPA 1995 was introduced in the NPA in 1977 (Parliamentary Papers 13209, 1975-1976, no. 8).

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):

Prior use, i.e., the use as meant in art. 55(1) NPA 1995, is defined as: ‘Any party who, in The Netherlands, Curaçao or Sint Maarten, has already manufactured or applied or commenced implementation of his intention to manufacture or apply, in or for his business,..’. The prior use of art. 55(1) NPA 1995 is territorially limited, i.e., only prior use in the Kingdom of The Netherlands is taken into account.

Use in the sense of art. 53(6) NPA 1995 is defined as “A product within the meaning of paragraph (1)(a) or (b) of art. 53 NPA 1995 that was manufactured in a business..’. Use after filing or priority date but before grant of the patent, is interpreted restrictively according to case law. For example, from Supreme Court, 23 juni 1995, *NJ* 1996, 463 (ARS/Organon) it can be concluded that use of medicines by the manufacturer in clinical trials in hospitals does not fall within the scope of art. 53(6) NPA 1995.

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

Prior use of art. 55(1) or 55(3) NPA 1995: no remuneration.

Prior use of art. 53(6) NPA 1995: according to art. 71 and 72 NPA 1995, for use after the filing or priority date, but before grant of the patent, the patentee may demand a reasonable compensation (see also question 2).

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

Yes
X No

According to art. 55(4) NPA 1995, the prior use right of art. 55 (1) and 55(3) NPA 1995 may only be transferred to third parties as part of a transfer of the 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?

Yes
No

If yes, please explain what those conditions are: Not applicable.

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?

X Yes
No

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

According to art. 23(5) NPA 1995, a party will remain authorised, notwithstanding the patent, to continue performing the acts stipulated in art. 53(1) NPA 1995 if the party in question has commenced, in or for his business, manufacturing or using an item in respect of which a patent is in force as a result of the restoration or has commenced implementing his decision to do so within the Netherlands or Curaçao or Sint Maarten in the period between the loss of rights or means of redress and the restoration to the prior situation.

According to art. 112a(6) of the European Patent Convention, concerning a petition for review by the Enlarged Board of Appeal, any person who, in a designated Contracting State, has in good faith used or made effective and serious preparations for using an invention which is the subject of a published European patent application or a European patent in the period between the decision of the Board of Appeal and publication in the European Patent Bulletin of the mention of the decision of the Enlarged Board of Appeal on the petition, may without payment continue such use in the course of his business or for the needs thereof.

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

The prior user of art. 55(1) NPA 1995 should not have obtained his knowledge from matter already made or applied by the applicant or from the applicant's descriptions, drawings or models. The prior user of art. 55(3) NPA 1995 should act in good faith.

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:

Art. 112a(6) of the European Patent Convention has not yet been implemented in the NPA 1995.

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

See above.

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):

According to art. 54 NPA 1995 the exclusive right of the patent owner shall not include: .
(a) the use on board vessels of other countries of the subject matter of the patent in the body of the vessel or in the machinery, rigging, tackle and other accessories thereof when such vessels are in the waters of the Netherlands or Curaçao or Sint Maarten temporarily or accidentally, provided that the use is for the actual needs of the vessel only;
(b) the use of the subject matter of the patent in the construction or operation of aircraft or land vehicles or of the accessories of such aircraft or land vehicles belonging to other countries, when such aircraft or land vehicles are in the Netherlands or Curaçao or Sint Maarten temporarily or accidentally; or
(c) the acts specified in Article 27 of the Chicago Convention on International Civil Aviation of 7 December 1944 (Dutch Bulletin of Acts and Decrees, 1947, H 165), provided that those acts relate to an aircraft of a State other than the Kingdom of The Netherlands as mentioned under (c) in that Article.

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

Not applicable.

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

Smooth running of international traffic.

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

Parliamentary Papers 197, 1904-1905, no. 3.

45. The exception applies in relation to:

X Vessels
X Aircrafts
X 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):

Yes, the exception applies to vehicles “temporarily” or “accidentally” present. There is no definition available.

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):

With respect to (a): use is allowed for the actual needs of the vessel only.
With respect to (b): in the construction or operation of aircraft or land vehicles or of the accessories of such aircraft or land vehicles.

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):

Not applicable.

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:

No amendments foreseen.

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

Not applicable.

Section VII: Acts for obtaining regulatory approval from authorities

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

According to art. 53(4) NPA 1995, the performance of necessary studies, tests and experiments in connection with the application of Article 10(1) to (4) of Directive 2001/83/EC on the Community Code relating to medicinal products for human use (Official EC Journal L 311) or Article 13(1) to (5) of Directive 2001/82/EC on the Community Code relating to veterinary medicinal products (Official EC Journal L 311) and the ensuing practical requirements shall not be deemed to constitute an infringement of patents relating to medicinal products for human use or medicinal products for veterinary use, respectively.
This Bolar type exception is an implementation of art. 10(6) of the EU Directive 2004/27/EC and art. 13(6) of EU Directive 2004/28/EC.

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

Relevant case law regarding the Bolar type exception stems from before the date of implementation of art. 53(4) NPA 1995 in the NPA. In the Supreme Court case of 23 June 1995, *BIE* 1997/41, (ARS/Organon) it was decided that clinical trials do not fall under the scope of the research exception. With that decision the existing research exception was interpreted in a narrow way. See also the case law discussed under section III above regarding the research exception.

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

The Directives referred to in art. 53(4) NPA 1995 require that applications for authorization to place a medicinal product on the market have to be accompanied by a dossier containing particulars and documents relating to the results of tests and clinical trials carried out on the product and thus proving its quality, safety and efficacy. Nevertheless, under certain conditions, it is sufficient if an applicant demonstrates that the medicinal product is a generic of a reference medicinal product which is or has been authorized. According to the Directives, conducting the necessary tests and trials for demonstrating the equivalence shall not be regarded as contrary to patent rights or to supplementary protection certificates (SPC) for medicinal products.
Without this Bolar-provision, which is implemented in art. 53(4) NPA 1995, the necessary tests and trials for demonstrating the equivalence could only start after expiration of the patent right or SPC relating to the reference medicinal product. As such tests and trials can take several months, in practice the duration of the patent or SPC protection would effectively be extended, which is considered to be an unintentional effect of patent law in relation to the market entrance of generic medical products.

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

Parliamentary Papers 30663, 2005-2006, nr. 3.

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

The exception is meant for the manufacturers of generic medicinal products.

55. The exception covers the regulatory approval of:

any products
X certain products. Please describe which products: medicinal products for human use or medicinal products for veterinary use.

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

Making
Using
Selling
Offering for sale
Import
Export
X Other. Please specify: the performance of necessary studies, tests and experiments for demonstrating the equivalence between a generic and reference medical product, the reference medical product being protected by a patent right or SPC.

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):

Not applicable.

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:

No amendments foreseen.

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

The precise scope of the exception is yet unclear, as the European Court of Justice has not ruled on the Bolar exception yet.. Historically, the Dutch courts have interpreted the scope of the 'old' research exemption quite narrow, especially with regard to clinical trials. It will be interesting to see how the new provision of article 10(6) of Directive 2004/27/EC will be interpreted in the near future. For instance, it is unclear which "trials and studies" are exempted and which activities constitute "consequential practical requirements". Does this include for instance stock-piling or taking pre-orders?

The Court of Appeal The Hague (case 105.007.171/01, 2 November 2010,) ruled recently on the question whether publication of a generic medicine in the G standard constitutes an act of infringement. The G standard is a Dutch database for available medicines. Users of the database were informed by the generic manufacturer that the generic medicine in question would only be available after expiry of the patent covering the original medicine. The Dutch court nevertheless decided that publication in the G standard is not exempted and therefore infringes the patent. It appeared that the Dutch court did not take the provision of Directive 2004/27/EC into account, despite the fact that the provision was already implemented into national legislation.

Section VIII: Exhaustion of patent rights

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

National
X Regional
International
Uncertain, please explain

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

According to art. 53(5) NPA 1995, if a product as referred to in art. 53(1) NPA 1995 has been put on the market lawfully in the Netherlands or Curaçao or Sint Maarten or in one of the Member States of the European Union or in another State that is party to the Agreement concerning the European Economic Area by the patent holder or with his consent, the person who obtains or later holds the product shall not be deemed to have contravened the patent by using, selling, hiring out or delivering that product or by otherwise dealing in it in or for his business, or by offering, importing, or stocking the product for any of those purposes.

With respect to exclusive rights relating to biological material (provided for in art. 53a NPA 1995, see also question 2), art. 53b NPA 1995 states that the exclusive right shall not include biological material that is obtained by propagation or by multiplication of biological material that has been put on the market lawfully in the Netherlands or Curaçao or Sint

Maarten or in one of the Member States of the European Union or in another State that is party to the Agreement concerning the European Economic Area by the patent holder or with his consent if the propagation or multiplication necessarily ensues from the use for which the biological material has been put on the market, provided that the derived material is not subsequently used for other propagations or multiplications.

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

From case law it has become clear that for the exhaustion it is decisive whether or not a product has been put on the market lawfully:
Supreme Court, 6 March 1936, *NJ* 1936, 588 and Supreme Court, 6 June 1941, *NJ* 1941, 812 : products put on the market under a compulsory license or prior use are deemed to be lawfully put on the market.
ECJ, 9 July 1985, *NJ* 1985, 456; *BIE* 1986/49 (Pharmon/Hoechst): for the European Union, products put on the market in another country under a compulsory license are deemed not to be put lawfully on the market. Therefore these products may only be imported with the consent of the patentee.

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

Exhaustion within the Netherlands: to limit the benefits of a patent to a single sale and prevent the patent holder of exercising complete control over the life span of a patented product.
Exhaustion within the European Economic Area: to allow for a free market across the European member states. This provision has developed in the case law of the European Court of Justice, e.g. ECJ, 31 October 1974, *NJ* 1975, 58; *BIE* 1975/1 (Centrafarm/Sterling Drug).

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

Exhaustion within the Netherlands: Parliamentary Papers 197, 1904-1905, no. 3.
Exhaustion within the European Economic Area: Parliamentary Papers 22604, 1991-1992, no. 3.

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
X Uncertain

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

As far as known, there is no relevant case law.

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

There are no amendments to the NPA foreseen in this respect.

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

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):

Subject to specific conditions, the following exceptions are contained in the NPA 1995:

Public interest
If the Minister of Economic affairs considers it in the public interest he may grant a licence under a patent to a party that he designates (see art. 57(1) NPA 1995).

Non-usus
If, after three years have elapsed since the grant of the patent, neither the patent holder nor any other party who has been granted a licence operates an industrial establishment in the Kingdom in which the product concerned is being made or where the process concerned is being applied in good faith and on a sufficient scale, the patent holder shall be obliged to grant the licence needed for operating such an establishment unless valid reasons are shown to exist for the absence of such an establishment (see art. 57(2) NPA 1995).

Dependent patent
The patent holder is obliged at all times to grant a licence required for the use of a patent granted in respect of an application that has the same or a later date of filing insofar as the patent for which the licence is requested represents a considerable technical advance involving a considerable economic value. The scope of such a licence shall not extend further than is necessary for the use of the licensee's patent. The latter will be obliged to grant a reciprocal licence under his patent to the holder of the other patent. (see art. 57(4) NPA 1995).

Plant breeders
The patent holder shall grant a plant breeder a licence in exchange for a reasonable fee if the plant breeder cannot obtain or exploit a plant breeder's right in respect of the plant variety without infringing the patent that was granted earlier and the licence is necessary for the exploitation of the plant variety to be protected, which represents a significant technical advance involving a considerable economic value in respect of the invention protected by the patent (see art. 57(5) NPA 1995).
If a patent holder is granted a licence on the ground of art. 42(2) of the Dutch Seeds and Planting Materials Act, the patent holder shall grant the holder of the plant breeder's right a reciprocal licence, at the latter's request, to use the protected invention subject to reasonable conditions (see art. 57(6) NPA 1995).

National security
In the interest of the defence of the Kingdom it may be provided by Royal Decree that the State shall be authorised to perform or cause others to perform acts, to be described precisely in that Decree, that the patent holder to be specified in that Decree has the exclusive right to perform pursuant to art. 53 and 53a NPA 1995 (see art. 59 NPA 1995).

Euratom treaty
A licence may be created by a decision of the Arbitration Tribunal referred to in art. 20 of the Treaty establishing the European Atomic Energy Community (EURATOM) (Treaty Bulletin 1957, 92) or a decision by the Minister of Economic Affairs pursuant to Article 21 of this treaty (see art. 60 NPA 1995).

Competitiveness
According to art. 31 TRIPs compulsory licenses could be used against anti-competitive practices.

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

Case law of the European Court of Justice regarding unfair competition: see ECJ, 16 December 1999, *BIE* 2001/72: the use of IP-rights can constitute unfair competition.

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

X Non-working or insufficient working of the patented invention (see art 57(2) NPA 1995)
Refusal to grant licenses on reasonable terms
X Anti-competitive practices and/or unfair competition (see art. 31 TRIPs, ECJ case law)
X Public health (if public interest, see art. 57(1) NPA 1995)
X National security (see art. 59 NPA 1995)
X National emergency and/or extreme urgency (if public interest, see art. 57(1) NPA 1995)
X Dependent patents (see art. 57(4) NPA 1995)
X Other, please specify:
- compulsory license for plant breeder (art. 57(5) and 57(6) NPA 1995)
- compulsory license as a result of the Euratom Treaty (art. 60 NPA 1995)

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

Exceptional circumstances and national security may put aside the rights of a patent holder. Furthermore, innovation would be hampered if a patent holder could prevent, by not providing licenses (for dependent patents), the use and further improvements on an invention. The provisions related to plant breeders are based on Directive 98/44/EG concerning the protection of biotechnological inventions.

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

Public interest, dependent patents: Parliamentary Papers 197, 1904-1905, no. 3.
National security: Parliamentary Papers 3451, 1953-1954, no. 3.
Non-usus, Euratom treaty: Parliamentary Papers 6429, 1960-1961, no. 3.
Plant Breeders: Parliamentary Papers 26568, 1998-1999, no. 3.

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):

Art. 57(2) NPA 1995: If, after three years have elapsed since the grant of the patent, neither the patent holder nor any other party who has been granted a licence operates an industrial establishment in the Kingdom or in another State to be designated by the Implementing Regulations in which the product concerned is being made or where the process concerned is being applied in good faith and on a sufficient scale, the patent holder shall be obliged to grant the licence needed for operating such an establishment

unless valid reasons are shown to exist for the absence of such an establishment. This obligation shall apply in respect of the holder of a European patent if, after three years have elapsed since the date on which the notification of the grant of the European patent was published in accordance with art. 97(4) of the European Patent Convention, an industrial establishment as referred to above is not in operation in the Netherlands or in the Curaçao or Sint Maarten or in another State to be designated by the Implementing Regulations.

According to art. 28 of the Implementing Regulations of the NPA 1995, art. 57(2) NPA 1995 includes all member states of the European Union, all states of the European Economic Space and those member states of the WHO where an industrial establishment as meant in art. 57(2) NPA 1995 is operated such that in the Kingdom the patented product, or the product manufactured by the patented process, is available on a sufficient scale.

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):

According art. 57(2) NPA 1995 juncto art. 28 of the Implementing Regulations and the case law of the National Patent Office (Special Board, 5 September 1995, *BIE* 1996/43) importation constitutes working of the patent.

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?

X Yes
No

If yes, what is the time period? Three years after the grant of the patent (see art. 57(2) NPA 1995).

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?

X Yes
No

If yes, what are "legitimate reasons"?

As far as known, there is no relevant case 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):

Not applicable.

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):

There are no legal provisions except for art. 31 TRIPs. As far as known, there is no case law related to patents.

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:

Art. 57(4) NPA 1995: The patent holder is obliged at all times to grant a licence required for the use of a patent granted in respect of an application that has the same or a later date of filing or, if a right of priority exists in respect of the application, the same or later date of priority, insofar as the patent for which the licence is requested represents a considerable technical advance involving a considerable economic value; however the patent holder will be obliged to grant a licence required for the use of a European patent only after the term for filing an opposition to the European patent has expired or after opposition proceedings thus instituted have ended. The scope of such a licence shall not extend further than is necessary for the use of the licensee's patent. The latter will be obliged to grant a reciprocal licence under his patent to the holder of the other patent.

A license should be required for use of the dependent patent; a license is required if without it exploitation of the patent would be technically and economically unfeasible, see case law of the National Patent Office (Board of Appeal, 23 February 1984, *BIE* 1986/53 and Board of Appeal, 8 September 1986, *BIE* 1986/87).

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:

According to art. 57(4) NPA 1995 (dependent patent), the patentee obtains a cross-license.
According to art. 58(6) NPA 1995, on the ground of a claim brought by the initiating party, in the absence of agreement the court shall fix the fee that the licensee must pay to the patent holder.

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:

A compulsory license under art. 57(1) may be granted for reasons of public interest. According to the Decision of the Minister of Economic Affairs, BIE 1981, nr. 38, the objectives of the governmental policy belong to the public interest.

Until 2011 no licenses have been granted under this provision yet.

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

There is no information available.

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:

Art. 31 TRIPs has not yet been implemented in the NPA 1995. Compulsory licensing is rare, there are no further amendments foreseen.

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

Not applicable.

Government use

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

Pre-grant
According to art. 44(1) NPA 1995, concerning confidential patent applications, in the event that the Minister of Defence is of the opinion that it is in the interest of the defence of the Kingdom, for the State to use, put into practice or cause to be used or to be put into practice the subject matter of a confidential patent application, he may take measures to that effect after giving notice of the decision in question. That decision shall contain a precise description of the acts that the State must be able to perform or cause to be performed.

Post-grant
According to art. 59(1) NPA 1995, compulsory licenses for national security interests also cover a right for the government to use patented inventions.

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

Not applicable.

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
- [X] 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?

Providing the government a right to use the technology described in confidential patent applications or patented technology for national security objectives.

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

Art. 44(1) NPA 1995: Parliamentary Papers 7960, 1964-1965, no. 3.
Art. 59(1) NPA 1995: Parliamentary Papers 3451, 1953-1954, no. 3.

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:

Not applicable.

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

This information is not available.

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:

No amendments foreseen.

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

Not applicable.

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):

According to art. 53c NPA 1995, the sale of vegetable propagation material or another form of putting vegetable propagation material on the market by the patent holder or with his consent to a farmer for the purposes of agricultural exploitation implies a right for the latter party to use the products of his harvest for further propagation or multiplication by himself in his own company, with due observance of art. 14 of Regulation (EC) no. 2100/94 of the Council of the European Union of 27 June 1994 on Community plant variety rights (Official EC Journal L 227).
Furthermore, the sale of breeding cattle or another form of putting breeding cattle on the market by the patent holder or with his consent to a farmer implies for the latter party the right to use the cattle that is protected by a patent for agricultural purposes. This use is in any event taken to include making the animal or animal propagation material available for use in a farmer's agricultural company, but not selling within the context of or with a view to commercial cattle breeding.

The farmer's privilege for plant material (art. 53c(1)) constitutes the implementation of Directive nr. 98/44/EG of 6 July 1998 concerning the protection of biotechnological inventions. At the same time a farmer's privilege for animal material was implemented.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

Not applicable.

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

A farmer may use the products of his harvest for further propagation or multiplication by himself in his own company.

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

Parliamentary Papers 26568, 1998-1999, 26568, nr. 3.

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):

The scope of the exception is defined in art. 14 of Regulation (EC) no. 2100/94 and the implementing regulation no. 874/2009. For example:
- the farmer's privilege only applies to specific agricultural plant species;
- there shall be no quantitative restriction of the level of the farmer's holding to the extent necessary for the requirements of the holding;
- the product of the harvest may be processed for planting, either by the farmer himself or through services supplied to him, without prejudice to certain restrictions which Member States may establish regarding the organization of the processing of the said product of the harvest, in particular in order to ensure identity of the product entered for processing with that resulting from processing;
- small farmers shall not be required to pay any remuneration to the holder;
- other farmers shall be required to pay an equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area; the actual level of this equitable remuneration may be subject to variation over time, taking into account the extent to which use will be made of the derogation provided for in paragraph 1 in respect of the variety concerned;
- etc.

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:

No amendments foreseen.

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:

Not applicable.

Breeders' use of patented inventions

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

Not applicable.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

Not applicable.

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

Not applicable.

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

Not applicable.

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):

Not applicable.

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:

Recently the Dutch Association of plant breeders has started a public debate on the desirability of the introduction of a breeders exemption. They have pointed out that the pool of plant varieties available for further breeding activities has declined rapidly over the last decade, due to increasing existing patent rights. In preparation is the introduction of a limited breeders exception in the NPA 1995, This limited breeders exception will apply to the use of patented biological material for breeding purposes, i.e. to discover and develop new plant varieties. The exception will not apply to the commercial exploitation of new plant varieties that are acquired using patented biological material, at least as long as the biological material of that new variety possesses the specific traits that were produced by the invention concerned.

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:

See question 99.

Section XI: Other Exceptions and Limitations

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

Not applicable.

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):

Not applicable.

(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:

Not applicable.

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

Not applicable.

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?):

Not applicable.

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

Not applicable.

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:

Not applicable.

[End of Questionnaire]