Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: Norway
Office: Norwegian Industrial Property Office (NIPO)

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Section I: General

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

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

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

There is a common legal standard for all inventions, stated in the Norwegian Patents Act (15. December 1967 no.9) Sections 1 and 2.

A patent may be granted only for an invention in respect of which the following conditions are satisfied;
(a) the invention is new;
(b) it involves an inventive step;
(c) it is capable of industrial application;
(d) the invention is described sufficiently clear for a skilled person in the art to reproduce it.

An invention has to have technical effect, technical character and be reproducible.
Subject matters not regarded as inventions include anything which merely consists of:

1. **discoveries, scientific theories and mathematical methods;**
2. **aesthetic creations;**
3. **schemes, rules or methods for performing mental acts, playing games or doing business, or programs for computers;**

4. **presentations of information.**

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]

The Norwegian Patents Act Sections 1 (2), (4)-(6) and Section 1a and 1b.

A patent cannot be granted in respect of plant or animal varieties. Inventions that concern plants or animals may, however, be patentable if usage of the patent is not technically limited to one particular plant or animal variety.

A patent cannot be granted for what are essentially biological processes to produce plants or animals. An essentially biological process means, for the purpose of this legal text, a process, which consists entirely of natural phenomena such as crossing or selection.

A patent shall not be granted for methods for surgical or therapeutic treatment or diagnostic methods, practiced on humans or animals. This provision shall not prevent the grant of patents for products, including substances and compositions of substances, for use in such methods.

The human body, at all of the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, is not patentable.

Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality.

In particular, the following shall not be patentable:

1. **processes for cloning human beings,**
2. **processes for modifying the genetic identity of human sex cells,**
3. **use of human embryos for industrial or commercial purposes, and**
4. **processes for modifying the genetic identity of animals, which are likely to cause them, suffering without any substantial medical benefit to man or animal, including animals resulting from such process**.

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?

Exclusive rights granted with a patent are regulated in the Norwegian Patents Act Section 3.

The exclusive right conferred by a patent shall, with the exceptions referred to in the third paragraph, imply that no one but the patent holder may, without his consent, exploit the invention by:

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

1. **producing, offering for sale, putting on the market or using a product protected by the patent, or by importing or possessing the product for such purposes;**

2. **using or offering to use a process protected by the patent or, whilst knowing, or it being obvious from the circumstances, that the use of the process is prohibited without the consent of the patent holder, offering the process for use in this country;**

3. **offering for sale, putting on the market or using a product made by a process protected by the patent, or importing or possessing the product for such purposes.**

The exclusive right shall also imply that no one but the patent holder may, without his consent, exploit the invention by offering or supplying any person who is not entitled to exploit the invention in this country with the means for carrying out the invention, provided that the means relate to an essential element of the invention and the person supplying or offering the means knows, or it is obvious from the circumstances, that the means are suitable and intended for such exploitation. If the means are staple commodities, this provision shall only apply where the person offering or supplying the means attempts to induce the recipient to commit acts infringing the exclusive right provided for in the first paragraph. In relation to the provisions of this paragraph, persons exploiting the invention as referred to in the third paragraph, items 1, 3 or 4, shall not be considered entitled to exploit the invention.

The exclusive right shall not include:

1. **Exploitation outside the course of professional activity.**

2. **Exploitation of products protected by the patent which have been put on the market in the European Economic Area by the patent holder or with his consent, if this is not determined differently by regulation laid down by the King.**

3. **Exploitation by experiment relating to the subject matter of the invention.**

4. **Preparation in a pharmacy of a medicine in accordance with a prescription in individual cases, or acts carried out with a medicine so prepared.**

5. **Tests, experiments and the like on a patented medicine necessary to obtain marketing authorization for a medicine in a state party to the WTO Treaty.**

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;
X 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]

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

3 For example, in some countries where patent rights extend to propagated or multiplicated material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other

[Footnote continued on next page]

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

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

Section II: Private and/or non-commercial use

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

The Norwegian *Patents Act Section 1(1):*
Within any technical field, any person who has made an invention which is susceptible of industrial application, or his successor in title, shall, in accordance with this Act, have the right on application to be granted a patent for the invention and thereby obtain the exclusive right to exploit the invention commercially or operationally.
Private /non-commercial use is not included in the term "industrial" and is therefore exempted.

Also see the Norwegian Patents Act Section 3:
The exclusive right shall not include: Exploitation outside the course of professional activity.

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

Not relevant

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

The term "exploit" implies certain limitations regarding the kinds of activities comprised by the patent protection. Patent rights only aim to protect the right holder against commercial exploitation of the invention. There is a common interest in keeping non- commercial use in the public domain. The right holder is therefore not protected against exploitation of the invention as a knowledge base for research, experimenting or education. However, if the invention is aiming at use in connection with research or education, for instance a measuring device, such use of the invention will be included in the patent protection.

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

[Footnote continued from previous page]

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).

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):

No definition in applicable law

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):

There are no other criteria stated in statutory law or case law. However case law may give guidelines as to how statutory law shall be interpreted.

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

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

The Norwegian Patents Act Section 3 (3) no. 3
The exclusive right shall not include:.. Exploitation by experiment relating to the subject matter of the invention.

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

Not applicable

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

The main public policy objective for providing this exception is to encourage further innovation, not to hinder scientific progress.

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

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

No

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

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):

None

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**
- ☐ other, please specify: …

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):

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

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

No distinction

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):

The experiment must relate to the subject matter of the invention

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 IV*: *Preparation of medicines

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

The Norwegian Patents Act Section 3 no. 4

"***The exclusive right shall not include: (…) preparation in a pharmacy of a medicine in accordance with a prescription in individual cases, or acts carried out with a medicine so prepared."***

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

Not relevant

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

Preparation of medicines in pharmacies should be possible regardless of patent rights, as long as the preparation happens in connection with a prescription. Such practice is not common in Norway

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

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

Not specified in the law. Authorized personnel in a Pharmacy.

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

☐ Yes
X No

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

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):

No

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:

This Section is not in use, since preparation of medicine in pharmacies is no longer common in Norway.

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

No challenges

Section V: Prior use

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

The Norwegian Patents Act Section 4

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:

An invention which has been used by one person may be patented by another. If we did not have the exemption for prior use, the person who had used the invention would have to stop using it, because the use would be in conflict with the patent right. The prior user's investments would be lost, and this is unfavorable in the light of community economy.

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

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 Norwegian Patents Act Section 4, states:
"Anyone who, at the time when the patent application was filed, was exploiting the invention commercially in this country, may, notwithstanding the patent, continue the exploitation, whilst retaining its general character, provided that the exploitation does not constitute an evident abuse in relation to the applicant or his predecessor in title. Such right of exploitation shall also, on similar conditions, be enjoyed by anyone who had made substantial preparations for commercial exploitation of the invention in this country"

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?

X Yes
☐ No

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

X Yes
☐ No

If yes, please explain what those conditions are:

The right may only be transferred to others in conjunction with the enterprise in which it has arisen or in which the exploitation was intended.

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:

The Norwegian Patents Act 74

"Where a patent application which has been made available to the public in accordance with section 22 has been shelved or refused or if a patent has lapsed and the rights of the applicant are re-established according to the provisions of sections 72 or 73, the Norwegian Industrial Property Office shall publish a notice to that effect.
Where anyone, after final refusal of the application, expiration of the time limit for the resumption of the shelved application or after the lapse of the patent, but before the publication in accordance with the first paragraph has been made, has started to exploit the invention commercially in this country in good faith, he may, notwithstanding the patent, continue the exploitation whilst retaining its general character. Such right of exploitation shall also, on similar conditions, be enjoyed by anyone who has made substantial preparations to exploit the invention commercially in this country.

The right referred to in the second paragraph may only be transferred to others in conjunction with the enterprise in which it has originated or in which the exploitation was intended. "

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):

Not relevant

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 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):

The Patents Act Section 5:
"An invention may, notwithstanding a patent, be utilized on a foreign vehicle, vessel or aircraft in connection with the use of such means of transportation during their temporary or accidental stay in this country.

See also Regulations to the Norwegian Patents Act (Patent Regulation) Section 101:
"Section 101. Spare Parts and Accessories for Aircraft
Notwithstanding any granted patent, spare parts and accessories for aircraft may be imported into Norway and used in Norway for the repair of aircraft registered in a foreign state that is a party to the Convention on International Civil Aviation of December 7, 1944 (the Chicago Convention) and that is either a party to the Paris Convention on Protection of Intellectual Property of March 20, 1883, or has patent legislation that recognises inventions made by nationals of another state that is a party to the Chicago Convention and that provides such inventions with a level of protection that is essentially in conformity with the protection provided under the Paris Convention."

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

Not relevant

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

The provision shall ensure that patent rights do not obstruct international transport.

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

45. The exception applies in relation to:

X Vessels
X Aircrafts
X Land Vehicles
☐ Spacecraft

The Law does not explicitly apply to spacecrafts. However it may be interpreted to include spacecrafts if the situation should occur.

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. Patents Act Section 5 uses the term "temporary or accidental stay in this country".

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No

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):

There is no other criteria

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

None

Section VII: Acts for obtaining regulatory approval from authorities

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

Patents Act Section 3 (3) No. 5:
"The exclusive right shall not include (…)
Trials, experiments and similar of a patented medicine that are required to obtain a marketing authorization for a medicine in a state that is a contracting party to the agreement of 15 April 1994 on the establishment of the World Trade Organization (The WTO Agreement)."

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

Not relevant

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

The EEA agreement obliged Norway to harmonize its Patents Act to take account of Article 10(6) of Directive 2004/27/EC, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, cf. EEA agreement Protocol 28 Article 3 No. 4

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

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

Not specified in the law

55. The exception covers the regulatory approval of:

☐ any products
X certain products. Please describe which products: **patented medicines**

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:…

According to the legislative history to the provision, the following acts are permitted under Section 3 (3) No. 5: Any tests, clinical trials and similar of a patented medicine that are required to obtain a marketing authorization for a medicine in a state that is a contracting party to the WTO agreement.
The exception only limits the exclusive right of the patented medicine itself, and does not encompass patented methods, equipment or other tools necessary to the process. However, the exception applies regardless of whether the test in question relates to generic, further developed, or newly developed medicines. Under the exception, one can also produce any amount necessary to fulfill any documentation requirements needed to obtain the marketing authorization in the particular WTO member state. The party seeking authorization will have the burden of proof.

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 relevant

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 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):

The Norwegian Patents Act Section 3 (3) No. 2:

The exclusive right shall not include:
Exploitation of products protected by the patent which have been put on the market in the European Economic Area by the patent holder or with his consent, if this is not determined differently by regulation laid down by the King.

Norwegian Patents Regulations Section 100
Limited Exhaustion for Medicinal Products Marketed in Individual EEA Member States:
A patent holder may refuse exploitation in Norway of patented medicinal products that have been brought on the market in Bulgaria, Estonia, Latvia, Lithuania, Poland, Rumania, Slovakia, Slovenia, the Czech Republic or Hungary by the patent holder himself or with the patent holder's consent if patent protection or a supplementary protection certificate cannot be obtained for the medicinal product in the country in question at the time at which the application for such protection was filed in Norway, cf. Section 3, third paragraph, no. 2, of the Patents Act.
Anyone who wishes to import into Norway a patented medicinal product in accordance with the first paragraph shall notify the patent holder or his successor in title hereof not later than one month before the application for a marketing license is filed, cf. Section 4- 8 b of Regulations No. 1559 of December 22, 1999 relating to medicinal products.

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

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

The European Economic Area (EEA) Agreement has obliged Norway to apply the rule of exhaustion to all products put on the market in the European Economic Area. See the EEA Agreement Article 11 and 13, which correspond to Article 34 and 36 of the Treaty on the Functioning of the European Union.

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

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

X No
☐ Uncertain

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

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:

We are not aware of any significant challenges

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):

The Norwegian *Patents Act Section 45 – 50a and the Norwegian Patent Regulations Section 97 – 100*

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

Not relevant

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
X Refusal to grant licenses on reasonable terms
X Anti-competitive practices and/or unfair competition
X Public health
X National security
X National emergency and/or extreme urgency
X Dependent patents
X Other, please specify: **Plant varieties (Norwegian Patents Act Section 46a)**

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

***The main objective is to meet important public interests. The patented invention should benefit the technical development and society. These objectives will not be met if the patentee represses the exploitation of the invention*.**

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

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 Norwegian Patents Act Section 45

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):

The term "work" refers to manufacturing activities like the production of the patented product or the use of the patented process. Import of the patented product from another country will consequently not necessarily prevent the grant of a compulsory license. However, in the case of import, the patentee may have legitimate reasons for the failure to work the invention in Norway

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?

Patents Act Section 45: "Where three years have elapsed from the grant of the patent and four years from the filing of the patent application without the invention being worked in this country to a reasonable extent"

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"?

This is an objective assessment. If the working of the invention has been impeded by public regulations, there might be legitimate reasons. If the patentee had difficulties in providing raw material or has been struggling with lack of resources, this cannot be considered as legitimate reasons.

73. ..If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

The Norwegian Patents Act Section 49 (1):
A compulsory license may only be granted to someone who has made efforts to obtain a license on reasonable business terms by agreement, without achieving it in reasonable

time, and may be presumed able to exploit the invention in a manner which is acceptable and which is in compliance with the terms of the license.
See also the Norwegian Patent Regulations Section 98.

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):

The Norwegian Patents Act Sections 50 and 50a

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:

The Norwegian Patents Act Section 46:
The holder of a patent for an invention, the use of which is dependent on a patent owned by someone else, may obtain a compulsory license to use the invention protected by the latter patent provided that the former invention involves an important technical advance of considerable economic significance in relation to the latter invention.
The holder of the patent for the invention to which the compulsory license applies shall be entitled to obtain a compulsory license on reasonable terms to use the other invention.

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:

The Norwegian Patents Act Section 50 (1)-(2):
The court shall grant a compulsory license in accordance with this section, and the Norwegian Competition Authority in accordance with Section 50 a.
In a decision considering a compulsory license, the court shall also determine to what extent the invention may be exploited and stipulate the compensation and the other terms of the license. The compensation shall be appropriate, taking into account the circumstances in each case. The value of the license shall be taken in consideration when assessing the compensation.

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

The Norwegian Patents Act Section 47:
Any person who wants to exploit an invention commercially, which has been patented by someone else, may be given a compulsory license
1. when required by important public interests.
2. when the patent rights are exploited in a way that significantly limits competition.

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

We are not aware of any compulsory licenses been granted in Norway for the last 40 years.

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):

The Norwegian Patents Act Sections 70 and the Act of 26th June 1953, relating to inventions which have significance for the defence of the kingdom Section 6 (1) og (2):

"Demand may be made, according to the decision of the King, that inventions which the King deems to have significance for the defence of the Kingdom be ceded to the authorities or other persons, when this is found desirable, in order that the invention may have the maximum utility for the defence. The same applies to the right to utilize such invention for a certain specified time.
For the same purpose the King may prohibit the owner of the right to dispose of an invention as mentioned in the first paragraph in a certain specified manner in this Kingdom or abroad, or enjoin on him certain specified duties in connection with the utilization. Prohibition or injunction pursuant to this paragraph holds good for such time as the King may determine."

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

Not relevant

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
- **X** Public health, **when required by important public interest**
- **X** National security
- **X** 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?

The Norwegian *Patents Act Section 70 and the Norwegian* Act of 26th June 1953, relating to inventions which have significance for the defence of the *Kingdom Section 6 (1) and (2): Secure the government the right to full disposal of an invention, which has significance for the defence of the Kingdom*.

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

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:

Patents Act Section 70: "war or danger of war and situations of crisis connected therewith"

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

Apparently never, according to legal commentators

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 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):

The Norwegian Patents Act Section 3b (1) and (3):

(1) If plant-propagating material is sold or transferred, with the consent of the patent holder, to a farmer for agriculture use this shall imply authorization for the farmer to use the product of his harvest for propagation or multiplication on his own farm notwithstanding Section 3 a paragraphs 1-3.

(2) **The King may, by regulation, determine the conditions and the extent of the farmer`s rights according to this Section.**

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 relevant

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

This exception allows farmers the right to use the product of their harvest for propagation or multiplication, even though the product is the harvest of protected varieties.

This is an exhaustion rule implemented in 2003. The farmer should not have to pay remuneration to the patentee for the harvest of protected varieties

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

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 Norwegian Patent Regulations Section 89-91

Section 89

A farmer's right to use plant-propagating material in accordance with section 3 b, first paragraph, of the Patents Act shall only apply to the following plant varieties:

1. ***Forage plants*: Cicer arietinum L. (chickpeas), Lupinus luteus L. (yellow lupin), Medicago sativa L. (lucerne), Pisum sativum L. (garden peas), Trifolium alexandrinum L. (alexandrine clover), Trifolium resupinatum L. (Persian clover), Vicia faba (fava bean) and Vicia sativa L. (garden vetch)**
2. ***Grain varieties*: Avena sativa (oat), Hordeum vulgare L. (barley), Oryza sativa L. (rice), Phalaris canariensis L. (canary grass), Secale cereale L. (rye), X Triticosecale Wittm. (rye wheat), Triticum aestivum L. emend. Fiori et Paol. (wheat), Triticum durum Desf. (durum wheat) and Triticum spelta L. (spelt wheat)**
3. ***Potatoes*: Solanum tuberosum (potatoes)**
4. ***Oil and fibre plants*: Brassica napus L. - partim - (rape), Brassica rapa L. - partim - (field mustard) and Linum usitatissimum (common flax).**

Section 90

No fee shall be payable for the exercise of the right in accordance with section 3 b, first paragraph, of the Patents Act if the propagating material is used on small farms. Small farms are farms that:

1. **do not cultivate potatoes in an area that exceeds the area necessary to produce 185 tonnes of potatoes per harvest, irrespective of the size of the area in which the farmer may cultivate other plants than potatoes**
2. **do not cultivate forage plants for a period of more than five years in an area that exceeds the area necessary to produce 92 tonnes of grain per harvest, irrespective of the size of the area in which the farmer may cultivate other plants than forage plants**
3. **do not cultivate the other plant varieties mentioned in section 89 of these Regulations in an area that exceeds the area necessary to produce 92 tonnes of grain per harvest, irrespective of the size of the area in which the farmer may cultivate other plants.**

Other farmers shall pay the rights holder a reasonable fee, which shall be significantly lower than the amount that may be charged for a licence to produce propagating material of the same type in the same area. Unless otherwise agreed, the fee shall correspond to 50 per cent of the amount that is charged for a licence of the type mentioned in the first period of this paragraph.

A farmer shall not pay a fee for use of breeding animals or other animal-propagating material in accordance with section 3 b, second paragraph, of the Patents Act.

Section 91

Unless otherwise agreed, the farmer shall, on request, provide the rights holder with information that is relevant for determining whether the requirements for applying the agricultural exemption in accordance with section 3 b, first paragraph, of the Patents Act, cf. sections 90 and 89 of these Regulations, have been complied with and for charging any fee in accordance with section 90, second paragraph. The information provided by the farmer shall include:

1. **the quantity of plant-propagating material that the farmer may have used in pursuance of section 3 b, first paragraph, of the Patents Act**
2. **the enterprise that may have produced the plant-propagating material for the farmer on the basis of the farmer's harvested products (the processing enterprise).**

Unless otherwise agreed, the processing enterprise shall, on request, provide the rights holder with information about the quantity of harvested products that the processing enterprise may have processed for the farmer and about the total quantity of plant-propagating material that has been produced on the basis of the harvested products. The right to request information shall only apply to information from the current production year and the three previous years.

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:

Yes

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:

None

Breeders' use of patented inventions

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

The Norwegian Patents Act Sections 3b (2).

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 relevant

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

Implementation of the EC Directive 98/44 the Legal Protection of Biotechnological Inventions. The breeder may use the protected animal or the reproductive material for an agriculture purpose on his own farm notwithstanding the exclusive rights of the patentee. This is an exhaustion rule implemented in 2003. The breeder should not have to pay remuneration to the patentee for such use.

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

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):

The Norwegian Patents Act Section 3b (2):
If breeding stock or other animal reproductive material is sold or transferred, with the consent of the patent holder, to a farmer, the farmer shall have the right to use the protected animal or the reproductive material for an agriculture purpose on his own farm notwithstanding section 3a paragraphs 1-3. The last sentence does not provide the right to sell the material referred to as a component of or for the purpose of commercial reproductive activity.

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:

Yes

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:

None

Section XI: Other Exceptions and Limitations

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

Biological material obtained by multiplication or propagation put on the market in the European Economic Area (EEA) by the patent owner for that purpose, other than for multiplication or propagation purposes. Use of biological material already existing in nature which is not necessary for the industrial application specified in the patent.

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):

The Norwegian *Patents Act Section 3a*
The protection referred to in paragraphs 1-3 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market within the EEA by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

Patents Act Section 3c:
The protection conferred by a patent on biological material, which already exists in nature, shall only extend to the part of the material that is necessary for the industrial

application specified in the patent application. It shall be evident from the patent application how the biological material may be used for industrial purposes.

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The Norwegian Patents Act Section 3a (4):
This section defines the scope of the exhaustion rule in Section 3(3) no. 2, as regards reproducible biological material, for instance seeds.
The legislative reason for the Norwegian law in Section 3a (4) is the EC Directive 98/44.

Patents Act Section 3c:
In principle, material already exciting in nature is considered as "discoveries" and may not be patented, see Section 1(2) no. 1. Section 3c forms an exception from this main rule. The section aims at precisely defining the scope of the patent protection for biological material already excising in nature.
The section corresponds to the rule in Section 1(1) stating that the invention must have technical effect.

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

Not defined

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?):

No

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

No

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:

Competition law

[End of Questionnaire]