

**Draft Questionnaire on Exceptions and Limitations to Patent Rights**

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

Country: UNITED STATES OF AMERICA.....  
Office: United States Patent and Trademark Office .....

Person to be contacted:

Name: .....  
Title: .....  
E-mail: .....  
Telephone: .....  
Facsimile: .....

**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.

**35 U.S.C. § 101: Inventions patentable.**

*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

**35 U.S.C. § 112: Specification.**

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

*A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.*

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\* Text proposed by the Delegation of the United States of America.

*Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.*

*A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.*

*An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.*

**35 U.S.C. § 102\*:** *Conditions for patentability; novelty.*

*(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—*

*(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or*

*“(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.*

*“(b) EXCEPTIONS.—*

*“(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—*

*“(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or*

*“(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.*

*“(2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—*

*“(A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;*

*“(B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor;*

*or*

*“(C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.*

*“(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.— Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—*

*“(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;*

*“(2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and*

*“(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.*

*(d) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.—For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—*

*“(1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or*

*“(2) if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.*

**35 U.S.C. § 103\*:** *Conditions for patentability; non-obvious subject matter. A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made..*

\* As amended by the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011). These sections are expected to take effect on March 16, 2013. ....

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Correspondingly, please list any exclusions from patentability that exist in your law. Furthermore, please provide the source of any 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.

Laws of nature, natural phenomena and abstract ideas are not eligible for patent protection.

*Diamond v. Diehr, 450 U.S. 175, 185 (1981).*

The recently passed Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), § 33, prohibits issuance of a patent on a claim directed to or encompassing a human organism.

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2.\* As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The patent owner has the exclusive right to prevent others from making, using, offering to sell, selling within the United States and importing into the United States any patented invention.

*35 U.S.C. 271 Infringement of patent.*

*(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.*

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

- Private and/or non-commercial use;
- X Experimental use and/or scientific research;
- Preparation of ~~prescribed~~ medicines;<sup>1</sup>
- 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;
- Exceptions and limitations related to ~~F~~farmer's' privilege and/or breeders' use of patented inventions.<sup>2</sup> ~~exception~~

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

\* Text proposed by the Delegation of the United States of America.

<sup>1</sup> For example, extemporaneous preparation of prescribed medicines in pharmacies.

<sup>2</sup> For example, certain uses by farmers of harvested plant material or of breeding life stock or other animal reproductive material under patent protection, or uses by breeders of patented biological material for the purpose of developing a new plant variety.

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**

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

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

N/A .....  
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46. (a) What is/are the rationale/public policy objectives for providing the exception?

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

.....  
N/A .....  
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57. 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):

N/A .....  
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68. 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):

N/A .....  
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79. 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:

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

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N/A.....  
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**Section III: Experimental use and/or scientific research <sup>3</sup>**

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

4012. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

*Madley v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002)  
Any use which has the slightest commercial implication or is in keeping with the legitimate business of the alleged infringer cannot qualify for the experimental use defense.

4413. (a) What is/are the rationale-public policy objectives for providing the exception?

To achieve an appropriate balance of rights  
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

4214. 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:

N/A  
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4315. If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):

The only experimental activities that qualify for this very limited defense are those involving experimentation solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.

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<sup>3</sup> Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

“... regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.” *Madley v. Duke*, 307 F.3d 1351, 1362 (Fed. Cir. 2002)

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4416. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

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

4517. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

- Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
- Research and/or experimentation must be conducted with or using the patented invention (“research with”)
- Both of the above

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

N/A

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4618. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

- A non-commercial purpose
- A commercial purpose
- Both of the above
- The commercial intention of the experimentation and/or research is not relevant

4719. 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):

*Madley v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002)

Any use which has the slightest commercial implication or is in keeping with the legitimate business of the alleged infringer” cannot qualify for the experimental use defense.

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4820. 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):

N/A

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4921. 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:

In view of the recent passage of a major patent reform bill (Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), it is very unlikely that any changes to the patent laws will be enacted during the remainder of this Congressional Term.

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2022. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A .....

**Section IV: Preparation of ~~prescribed~~ medicines**

2423. If the exception is contained in statutory law, please provide the relevant provision(s):

N/A .....

2224. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A .....

2325. (a) What ~~is~~ are the ~~rational~~ rationale public policy objectives for providing the exception? Please explain:

N/A .....

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

N/A .....

2426. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

N/A .....

2527. Does the applicable law provide for any limitations on the amount of medicines that can be ~~produced~~ prepared under the exception?

- Yes
- No

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

N/A .....

~~26~~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):

N/A .....

~~27~~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:

N/A .....

~~28~~30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A .....

**Section V: Prior use**

~~29~~31. If the exception is contained in statutory law, please provide the relevant provision(s):

*35 USC § 273\*. Defense to infringement based on prior commercial use*

*(a) IN GENERAL.—A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—*

*“(1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm’s length sale or other arm’s length commercial transfer of a useful end result of such commercial use; and*

*“(2) such commercial use occurred at least 1 year before the earlier of either—*

*“(A) the effective filing date of the claimed invention;*

*or*

*“(B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).*

*“(b) BURDEN OF PROOF.—A person asserting a defense under this section shall have the burden of establishing the defense by clear and convincing evidence.*

*“(c) ADDITIONAL COMMERCIAL USES.—*

*“(1) PREMARKETING REGULATORY REVIEW.—Subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or*

*efficacy of the subject matter is established, including any period specified in section 156(g), shall be deemed to be commercially used for purposes of subsection (a)(1) during such regulatory review period.*

*“(2) NONPROFIT LABORATORY USE.—A use of subject matter by a nonprofit research laboratory or other nonprofit entity, such as a university or hospital, for which the public is the intended beneficiary, shall be deemed to be a commercial use for purposes of subsection (a)(1), except that a defense under this section may be asserted pursuant to this paragraph only for continued and noncommercial use by and in the laboratory or other nonprofit entity.*

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*“(e) LIMITATIONS AND EXCEPTIONS.—*

*“(1) PERSONAL DEFENSE.—*

*“(A) IN GENERAL.—A defense under this section may be asserted only by the person who performed or directed the performance of the commercial use described in subsection (a), or by an entity that controls, is controlled by, or is under common control with such person.*

*“(B) TRANSFER OF RIGHT.—Except for any transfer to the patent owner, the right to assert a defense under this section shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.*

*“(C) RESTRICTION ON SITES.—A defense under this section, when acquired by a person as part of an assignment or transfer described in subparagraph (B), may only be asserted for uses at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business.*

*“(2) DERIVATION.—A person may not assert a defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee.*

*“(3) NOT A GENERAL LICENSE.—The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter for which it has been established that a commercial use that qualifies under this section occurred, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.*

*“(4) ABANDONMENT OF USE.—A person who has abandoned commercial use (that qualifies under this section) of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken on or after the date of*

*such abandonment.*

*“(5) UNIVERSITY EXCEPTION.—*

*“(A) IN GENERAL.—A person commercially using subject matter to which subsection (a) applies may not assert a defense under this section if the claimed invention with respect to which the defense is asserted was, at the time the invention was made, owned or subject to an obligation of assignment to either an institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more such institutions of higher education.*

*(B) EXCEPTION.—Subparagraph (A) shall not apply if any of the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the Federal Government.*

*“(f) UNREASONABLE ASSERTION OF DEFENSE.—If the defense under this section is pleaded by a person who is found to infringe the patent and who subsequently fails to demonstrate a reasonable basis for asserting the defense, the court shall find the case exceptional for the purpose of awarding attorney fees under section 285.*

*“(g) INVALIDITY.—A patent shall not be deemed to be invalid under section 102 or 103 solely because a defense is raised or established under this section.”.*

*(b) CONFORMING AMENDMENT.—The item relating to section 273 in the table of sections for chapter 28 of title 35, United States Code, is amended to read as follows:*

*“273. Defense to infringement based on prior commercial use.”.*

*(c) EFFECTIVE DATE.—The amendments made by this section shall apply to any patent issued on or after the date of the enactment of this Act.*

\* As amended by the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011). These sections are expected to take effect on January 16, 2012.

3032. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A .....

3433. (a) ~~What is~~ are the rationale-public policy objectives for providing the exception? Please explain:

To achieve an appropriate balance of rights .....

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

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N/A .....  
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3234. 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):

*35 USC § 273\*. Defense to infringement based on prior commercial use*

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*“(1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm’s length sale or other arm’s length commercial transfer of a useful end result of such commercial use; and*

*“(2) such commercial use occurred at least 1 year before the earlier of either—*

*“(A) the effective filing date of the claimed invention;*

*or*

*“(B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).*

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*“(c) ADDITIONAL COMMERCIAL USES.—*

*“(1) PREMARKETING REGULATORY REVIEW.—Subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established, including any period specified in section 156(g), shall be deemed to be commercially used for purposes of subsection (a)(1) during such regulatory review period.*

*“(2) NONPROFIT LABORATORY USE.—A use of subject matter by a nonprofit research laboratory or other nonprofit entity, such as a university or hospital, for which the public is the intended beneficiary, shall be deemed to be a commercial use for purposes of subsection (a)(1), except that a defense under this section may be asserted pursuant to this paragraph only for continued and noncommercial use by and in the laboratory or other nonprofit entity.*

\* As amended by the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011). These sections are expected to take effect on January 16, 2012.

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3335. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

N/A .....

~~34~~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

~~35~~37. In case of affirmative answer to question ~~34~~36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

X Yes  
No

If yes, please explain what those conditions are:

Section 273 provides that the defense may be asserted only by the person who performed or directed the performance of the commercial use or by an entity that controls, is controlled by, or is under common control with such person. With respect to transfer of rights, Section 273 specifically provides that the right to transfer the defense is limited to transfer of rights by assignment or transfer of the entire enterprise or business to which the defense relates. However, a person may not assert the defense if subject matter was derived from patentee or persons in privity with the patentee.

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~~36~~38. Does ~~the this prior use~~ exception continue to apply in ~~the~~ situations where ~~the a third party~~ prior user has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes  
X No

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

N/A .....

~~37~~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):

Section 273 provides that the defense is only available for commercial activities in the United States.

Section 273(e) provides the following limitations and exceptions:

- (1) PERSONAL DEFENSE-
- (A) IN GENERAL- A defense under this section may be asserted only by the person who performed or directed the performance of the commercial use described in subsection

(a), or by an entity that controls, is controlled by, or is under common control with such person.

(B) TRANSFER OF RIGHT- Except for any transfer to the patent owner, the right to assert a defense under this section shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.

(C) RESTRICTION ON SITES- A defense under this section, when acquired by a person as part of an assignment or transfer described in subparagraph (B), may only be asserted for uses at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business.

(2) DERIVATION- A person may not assert a defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee.

(3) NOT A GENERAL LICENSE- The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter for which it has been established that a commercial use that qualifies under this section occurred, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.

(4) ABANDONMENT OF USE- A person who has abandoned commercial use (that qualifies under this section) of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken on or after the date of such abandonment .....

Section 273(a)(2) provides that the defense is available to commercial uses that occurred at least one year before the effective filing date of the claimed invention or the public disclosure date.....

~~384~~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:

The recently passed Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), revised 35 U.S.C. § 273.

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

N/A .....

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

4042. If the exception is contained in statutory law, please provide the relevant provision(s):

*35 USC 272. Temporary presence in the United States*

*The use of any invention in any vessel, aircraft or vehicle of any country which affords similar privileges to vessels, aircraft or vehicles of the United States, entering the United States temporarily or accidentally, shall not constitute infringement of any patent, if the invention is used exclusively for the needs of the vessel, aircraft or vehicle and is not offered for sale or sold in or used for the manufacture of anything to be sold in or exported from the United States.*

4143. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

4244. (a) What are the rational public policy objectives for providing the exception? Please explain:

To achieve an appropriate balance of rights

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

N/A

4345. The exception applies in relation to:

Vessels  
Aircrafts  
Land Vehicles  
Spacecraft

*. . . any vessel, aircraft or vehicle of any country which affords similar privileges to vessels, aircraft or vehicles of the United States, entering the United States temporarily or accidentally. . . 35 USC § 272*



4446. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The Federal Circuit interpreted "entering the United States temporarily" in § 272 as meaning "entering for a period of time of finite duration with the sole purpose of engaging in international commerce." A vessel, aircraft or vehicle entering to unload foreign goods and/or to load domestic goods destined for foreign markets, is entering "temporarily" for the purposes of section 272.

*NATIONAL STEEL CAR, LTD. v. CANADIAN PACIFIC RY., 357 F.3d 1319 (2004)*

4547. 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):

*. . . if the invention is used exclusively for the needs of the vessel, aircraft or vehicle and is not offered for sale or sold in or used for the manufacture of anything to be sold in or exported from the United States. 35 USC 272*

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.....

4648. 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):

N/A

4749. 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:

In view of the recent passage of a major patent reform bill (Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), it is very unlikely that any changes to the patent laws will be enacted during the remainder of this Congressional Term.

.....  
.....

4850. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A.....  
.....  
.....

**Section VII: Acts for obtaining regulatory approval from authorities**

4951. If the exception is contained in statutory law, please provide the relevant provision(s):

.....  
.....  
.....

35 USC §271(e)(1)

*It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.*

5052. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

.....  
35 USC § 271(e)(1) exempts from infringement the use of patented inventions reasonably related to the development and submission of information needed to obtain marketing approval of medical devices under the FDCA. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665-679 (1990)  
.....

5153. (a) ~~What is are the rationale~~ What are the rationale public policy objectives for providing the exception? Please explain:

.....  
To achieve an appropriate balance of rights .....  
.....

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

N/A .....  
.....  
.....

5254. Who is entitled to use the exception? Please explain:

Those whose actions are “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products” 35 USC §271(e)(1) .....  
.....  
.....

5355. The exception covers the regulatory approval of:

- any products
- X certain products.

Please describe which products:

*Drugs or veterinary biological products.*  
*35 USC §271(e)(1)*

5456. Please indicate which acts are allowed in relation to the patented invention under the exception?

- X Making
- X Using
- X Selling
- X Offering for sale
- X Import
- X Export

Other. Please specify:.....

5557. 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):

.....  
.....

5658. 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:

In view of the recent passage of a major patent reform bill (Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), it is very unlikely that any changes to the patent laws will be enacted during the remainder of this Congressional Term.

.....  
.....

5759. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A.....  
.....  
.....

**Section VIII: Exhaustion of patent rights**

5860. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

- X National
- Regional
- International
- Uncertain, please explain.....

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

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

*Adams v. Burke, 84 U.S. 453(1873)*

"[W]hen the patentee, or the person having his rights, sells a machine or instrument whose sole value is in its use, he receives the consideration for its use and he parts with the right to restrict that use." .....

5961. (a) ~~What is~~ are the rationale-public policy objectives for adopting the exhaustion regime specified above? Please explain:

To achieve an appropriate balance of rights. The patentee receives his reward by his first sale of the product, after which he has no claim to control commerce in that already-sold product. *See Adams v. Burke, 84 U.S. 453(1873)* .....

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

N/A .....

6062. 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):

The unauthorized importation in the United States of a patented device that was sold outside of the United States is not shielded from infringement by the patent exhaustion doctrine.

*See e.g. Fujifilm Corp v. Benun, 605 F.3d 1366, 1371-72 (Fed. Cir. 2010)*

6163. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

In view of the recent passage of a major patent reform bill (Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), it is very unlikely that any changes to the patent laws will be enacted during the remainder of this Congressional Term.

6264. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

N/A .....

**Section IX: Compulsory licenses and/or government use**

Compulsory licenses

~~63~~65. If the exception is contained in statutory law, please provide the relevant provision(s):

Different sections of law are applicable, depending on the circumstances of a situation.

The following provision concerns licensing of air pollution prevention inventions under Title 40: Protection of Environment.

40 C.F.R. § 95.2 *Petition for mandatory license.*

*(a) Any party required to comply with sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521) may petition to the Administrator for a mandatory patent license pursuant to section 308 of the Act (42 U.S.C. 7608), under a patent that the petitioner maintains is necessary to enable the petitioner to comply with Sections 111, 112 or 202 of the Act.*

*(b)(1) Each petition shall be signed by the petitioner and shall state the petitioner's name and address. If the petitioner is a corporation, the petition shall be signed by an authorized officer of the corporation, and the petition shall indicate the state of incorporation. Where the petitioner elects to be represented by counsel, a signed notice to that effect shall be included with the petition at the time of filing.*

*(2) Each petition shall include a copy of the patent under which a mandatory patent license is sought. The petition shall identify all current owners of the patent and shall include a copy of all assignment documents relevant to the patent that are available from the United States Patent and Trademark Office.*

*(3) Each petition must identify any person whose interest the petitioner believes may be affected by the grant of the license to which the petition is directed.*

*(4) Each petition must contain a concise statement of all of the essential facts upon which it is based. No particular form of statement is required. Each petition shall be verified by the petitioner or by the person having the best knowledge of such facts. In the case of facts stated on information and belief, the source of such information and grounds of belief shall be given. The statement of facts shall include the following:*

*(i) An identification of the provisions of the Act and/or regulations thereunder that the petitioner maintains petitioner will be able to comply with if the petitioner is granted the patent license that is the subject of the petition;*

*(ii) An identification of the nature and purpose of the petitioner's intended use of the patent license;*

*(iii) An explanation of the relationship between the patented technology and the activities to which petitioner proposes to apply the patented technology, including an estimate of the effect on such activities stemming from the grant or denial of the patent license;*

*(iv) A summary of facts demonstrating that the patent under which a mandatory patent license is sought is being used or is intended for public or commercial use;*

*(v) An explanation of why a mandatory patent license is necessary for the petitioner to comply with the requirements of sections 111, 112 or 202 of the Act, and why the patented technology is not otherwise available;*

*(vi) An explanation of why there are no other reasonable alternatives for accomplishing compliance with sections 111, 112 or 202 of the Act;*

*(vii) An explanation of why the unavailability of a mandatory patent license may result in a substantial lessening of competition or a tendency to create a monopoly in any line of commerce in any section of the United States;*

(viii) A summary of efforts made by the petitioner to obtain a patent license from the owner of the patent, including the terms and conditions of any patent license proposed by petitioner to the patent owner; and

(ix) The terms, if any, on which the owner of the patent has proposed to grant the petitioner a patent license.

(5) Each petition shall include a proposed patent license that states all of the terms and conditions that the petitioner proposes for the patent license.

(6) Petitions shall be addressed to the Assistant Administrator for Air and Radiation, Mail Code 6101, U.S. Environmental Protection Agency, Washington, DC 20460.

(c) Petitions that do not include all of the information required in paragraph (b) of this section shall be returned to the petitioner. The petitioner may supplement the petition and resubmit the petition.

(d) If the Administrator, or the Administrator's designee, finds that the criteria in §95.3 are not met, or otherwise decides to deny the petition, a denial of the petition shall be sent to the petitioner, along with an explanation of the reasons for the denial.

(e) If the Administrator, or the Administrator's designee, finds that the criteria in §95.3 are met and decides to apply to the Attorney General for a patent license under section 308 of the Act, notice of such application shall be given to the petitioner, along with a copy of the application sent to the Attorney General.

The following section specifies the provisions relating to anti-competitive aspects of US patents on specified pollution control systems.

#### **42 USC § 7608**

*Whenever the Attorney General determines, upon application of the Administrator—*

*(1) that—*

*(A) in the implementation of the requirements of section 7411, 7412, or 7521 of this title, a right under any United States letters patent, which is being used or intended for public or commercial use and not otherwise reasonably available, is necessary to enable any person required to comply with such limitation to so comply, and*

*(B) there are no reasonable alternative methods to accomplish such purpose, and*

*(2) that the unavailability of such right may result in a substantial lessening of competition or tendency to create a monopoly in any line of commerce in any section of the country, the Attorney General may so certify to a district court of the United States, which may issue an order requiring the person who owns such patent to license it on such reasonable terms and conditions as the court, after hearing, may determine. Such certification may be made to the district court for the district in which the person owning the patent resides, does business, or is found.*

The following provision concerns licensing of technology related to special nuclear material or atomic energy.

#### **42 USC § 2183. Nonmilitary utilization**

*(a) Declaration of public interest*

*The Commission may, after giving the patent owner an opportunity for a hearing, declare any patent to be affected with the public interest if*

*(1) the invention or discovery covered by the patent is of primary importance in the production or utilization of special nuclear material or atomic energy; and (2) the licensing of such invention or discovery under this section is of primary importance to effectuate the policies and purposes of this chapter.*

*(b) Action by Commission*

*Whenever any patent has been declared affected with the public interest, pursuant to subsection*

(a) of this section—

(1) the Commission is licensed to use the invention or discovery covered by such patent in performing any of its powers under this chapter;  
and

(2) any person may apply to the Commission for a nonexclusive patent license to use the invention or discovery covered by such patent, and the Commission shall grant such patent license to the extent that it finds that the use of the invention or discovery is of primary importance to the conduct of an activity by such person authorized under this chapter.

6466. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A .....

6567. What grounds for the grant of a compulsory license (~~CL~~) and/or government use (~~GU~~) does the applicable law provide in respect to patents (please indicate the applicable grounds):

~~CL~~—~~GU~~

- Non-working or insufficient working of the patented invention
- Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- Public health
- National security
- National emergency and/or extreme urgency
  - Dependent patents
- Other, please specify: ...

Specific provisions under the Clean Air Act, and under the rules of the Nuclear Regulatory Commission, as indicated in question 65...

6668. (a) What is/are the rationale public policy objectives for providing compulsory licenses in your country? Please explain:

To achieve an appropriate balance of rights .....

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

N/A .....

6869. 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):

N/A .....  
.....  
.....

~~69~~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):

N/A .....  
.....  
.....

~~70~~71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes  
No

If yes, what is the time period? N/A .....

~~71~~72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes  
No

If yes, what are “legitimate reasons” N/A .....



~~7273.~~ 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):

N/A .....

~~7374.~~ 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 regulatory Agencies have used IP licensing as a remedy in three different types of antitrust cases. First, when the Antitrust Agencies have determined that a proposed merger is substantially likely to lessen competition, the Agencies may determine that an IP license to a particular purchaser of divested assets is necessary to maintain competition in a market. Or the Agencies may determine that an IP license is necessary generally to lower a barrier to entry after the merger by making a license available on reasonable terms to all interested potential competitors. IP licensing in the merger context is usually implemented with the consent of the parties.

Second, in a few cases, the Agencies have sought compulsory licenses to remedy competitive harm arising from specific uses of IP rights.

Third, in a few other cases, parties have similarly consented to granting IP licenses in order to remedy the effects of conduct proven to be anti-competitive that was not based on the anti-competitive use of IP rights.

.....

~~7475.~~ 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:

N/A .....

~~7576.~~ 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:

In general, a reasonable royalty has been held as the appropriate remedy. ....

~~7677.~~ If the applicable law provides for the grant of compulsory licenses ~~and/or 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:

N/A .....

.....  
.....

~~7778.~~ Please indicate how many times and in which technological areas compulsory licenses and/or government use have been issued in your country:

N/A.....

~~7879.~~ Is the applicable legal framework for the issuance of compulsory licenses and/or government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

.....  
In view of the recent passage of a major patent reform bill (Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), it is very unlikely that any changes to the patent laws will be enacted during the remainder of this Congressional Term.  
.....

~~7980.~~ Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system and/or government use provisions in your country? Please explain:

N/A.....  
.....

Government use

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

**28 USC § 1498 (a)**

*Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. Reasonable and entire compensation shall include the owner's reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action if the owner is an independent inventor, a nonprofit organization, or an entity that had no more than 500 employees at any time during the 5-year period preceding the use or manufacture of the patented invention by or for the United States. Notwithstanding the preceding sentences, unless the action has been pending for more than 10 years from the time of filing to the time that the owner applies for such costs and fees, reasonable and entire compensation shall not include such costs and fees if the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust.*

*For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States. . . . .*

6482. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

.....  
.....

6583. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

- Non-working or insufficient working of the patented invention
- Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- Public health
- National security
- National emergency and/or extreme urgency
- Dependent patents

X Other, please specify: ...

The United States Government may practice any patented invention "for the government" and subject to its obligation to provide reasonable compensation to the patent owner.

6684. (a) What are the public policy objectives for providing government use in your country?

To permit the United States Government to procure devices or services that it needs for its own governmental purposes while the courts determine whether a valid patent has been infringed and without necessitating an injunction.

.....  
.....

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

*See Richmond Screw Anchor Co. v. United States, 275 U.S. 331 (1928); Leesona Corp. v. United States, 599 F.2d 958 (Ct. Cl. 1979)* (These cases set forth a detailed discussion of the considerations that led to the enactment of the Acts of 1910 and 1918, which were the predecessors of section 1498(a)).

.....  
.....

7685. 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:

N/A .....

7786. Please indicate how many times and in which technological areas government use has been issued in your country:

This cannot be easily determined since governmental use is not "issued" as such, but rather involves the government being sued for alleged patent infringement and found liable for infringement under section 1498(a), or its predecessor. ....

.....

.....  
7887. 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:

.....  
In view of the recent passage of a major patent reform bill (Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), it is very unlikely that any changes to the patent laws will be enacted during the remainder of this Congressional Term.  
.....

7988. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

N/A.....  
.....  
.....

**Section X: Exceptions and limitations related to Farmer's' and/or breeder's' use of patented inventionsexception**

Farmers' use of patented inventions

8089. If the farmer's privilege in respect of patents exception is contained in statutory law, please provide the relevant provision(s):

Protection for asexually reproduced plants, except for tuber propagated plants and plants found in an uncultivated state, is provided by plant patents under 35 U.S.C. 161 Patents for plants.

With respect to utility patents and plant patents, there are no provisions for a Farmer's Privilege.

Protection for sexually reproduced plants is provided by the Plant Variety Protection Act. Administration of the Plant Variety Protection Act is not within the jurisdiction of the USPTO, but rather is under the jurisdiction of the Department of Agriculture.

The Plant Variety Protection Act provides as follows: .....

7 U.S.C. 2543. Right To Save Seed; Crop Exemption.

*Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 111, it shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. A purchaser who diverts seed from such channels to seeding purposes shall be deemed to have notice under section 127 that the actions of the purchaser constitute an infringement.*

8190. If the exception farmer's privilege in respect of patents is provided through case law, please cite the relevant decision(s) and provide ~~its~~(their)a brief summary of such decision(s):

N/A .....

8491. ~~(a) What is the rationale~~ (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions~~farmer's privilege in respect of patents?~~ Please explain:

.....  
To achieve an appropriate balance of rights .....

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

N/A .....

8692. ~~If the applicable law provides for the exception related farmer's privilege in respect of patents~~ Please explain its 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):

N/A .....

8893. ~~If the applicable law provides for the farmer's privilege in respect of patents, 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:

In view of the recent passage of a major patent reform bill (Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), it is very unlikely that any changes to the patent laws will be enacted during the remainder of this Congressional Term.

.....

9094. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions ~~farmer's privilege in respect of patents~~ in your country? Please explain:

N/A .....

Breeders' use of patented inventions

8295. If the exception breeder's exception in respect of patents is contained in statutory law, please provide the relevant provision(s):

Protection for asexually reproduced plants, except for tuber propagated plants and plants found in an uncultivated state, is provided by plant patents under 35 U.S.C. 161 Patents for plants.

With respect to utility patents and plant patents, there are no provisions for Breeder's Use.

Protection for sexually reproduced plants is provided by the Plant Variety Protection Act. Administration of the Plant Variety Protection Act is not within the jurisdiction of the USPTO, but rather is under the jurisdiction of the Department of Agriculture. The Plant Variety Protection Act provides as follows: .....

7 U.S.C. 2544 . Research Exemption.

*The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this Act.*

~~8396.~~ If the exception breeder's exception in respect of patents is provided through case law, please cite the relevant decision(s) and provide ~~its~~(their)a brief summary of such decision(s):

.....  
N/A .....

~~8597.~~ (a) What is are the rationale public policy objectives for providing the exception related to breeders' use of patented inventions~~breeder's exception in respect of patents~~? Please explain:

.....  
To achieve an appropriate balance of rights .....

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

.....  
N/A .....

~~8798.~~ ~~the applicable law provides for the , p~~Please explain the its 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):

N/A .....

~~8999.~~ If ~~the applicable law provides for the breeder's exception in respect of patents, i~~s 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:

.....  
In view of the recent passage of a major patent reform bill (Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), it is very unlikely that any changes to the patent laws will be enacted during the remainder of this Congressional Term.  
.....

94100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions ~~breeder's exception in respect of patents~~ in your country? Please explain:

.....  
N/A.....  
.....



**Section XI: Other Exceptions and Limitations**

92101. Please list any other exceptions and limitations that your applicable patent law provides:

N/A .....

93102. 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):

N/A .....

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

N/A .....

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

N/A .....

In addition, in relation to each exception and limitation, please explain:

(iv) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

N/A .....

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

N/A .....

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:

U.S. competition law does not contain any language that specifically provides for or permits the granting of compulsory licenses to address anti-competitive effects arising from the use of intellectual property ("IP") rights. The U.S. Federal Trade Commission ("FTC") and Department of Justice Antitrust Division ("DOJ") [hereinafter, "Antitrust Agencies" or "Agencies"] seek reasonable and necessary remedies sufficient to address violations of U.S. antitrust laws.

In the United States, courts and the Antitrust Agencies have the authority to address anti-competitive uses of IP rights. The Antitrust Agencies are the two federal authorities in charge of enforcing U.S. antitrust laws to promote competition. When intellectual property rights are the focus of an investigation, the Agencies generally use a flexible, effects-based approach to antitrust analysis, known as the “rule of reason.” This approach allows the Agencies to assess an activity’s overall competitive significance on a case-by-case basis, taking into account its procompetitive efficiencies and its anti-competitive effects. See U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY §3.4 (1995), *available at* <http://www.justice.gov/atr/public/guidelines/0558.htm>.

The Agencies investigate possible anticompetitive practices, including those involving the use of IP rights. Although much of the underlying civil law enforcement by the two Agencies is the same, each Agency follows a different process. If the FTC believes that a person, a company, or companies have violated the law — or that a proposed merger may violate the law — it may attempt to obtain voluntary compliance by entering into a consent order with the party or parties in question. If a consent agreement cannot be reached, the FTC may issue an administrative complaint before an administrative law judge employed by the FTC, and/or seek injunctive relief in federal court. If an FTC administrative law judge finds a violation of law, he or she may issue a cease and desist order. An initial decision by an administrative law judge may be appealed to the Commission. Final decisions issued by the Commission may be appealed to a U.S. Court of Appeals and, ultimately, to the U.S. Supreme Court. If the Commission’s position is upheld, the FTC, in certain circumstances, may then seek consumer redress in court. If the company violates an FTC order, the Commission also may seek civil penalties or an injunction.

In some circumstances, the FTC can go directly to federal court to obtain an injunction, civil penalties, or consumer redress. For effective merger enforcement, the FTC may seek a preliminary injunction to block a proposed merger pending a full examination of the proposed transaction in an administrative proceeding. The injunction preserves the market’s competitive status quo.

In contrast, if DOJ believes that a person, a company or companies have violated the law — or that a proposed merger may violate the law — it institutes an action in federal court seeking a court order forbidding future violations of the law and requiring steps to eliminate the anti-competitive effects of past violations. DOJ may also seek a preliminary injunction in court to block a proposed merger to protect the market’s competitive status quo.

In many civil cases brought by DOJ, it is possible to obtain effective relief without having a trial. Such relief is designed to stop the illegal practices alleged in DOJ’s complaint, to prevent them from happening again, and to restore competition to the state that would have existed had the violation not occurred. Consent judgments are subject to public scrutiny and comment. In these cases, DOJ facilitates this review by providing the federal district court with a competitive impact statement in addition to the complaint and proposed final judgment. The competitive impact statement explains the reasons for the proceeding, the practices or events that led to the alleged violation, the reasons for which the proposed remedy is appropriate under the circumstances, and the reasons why the settlement benefits the public. The federal district court must approve the proposed settlement if it is within the public interest. Decisions by a court in both settled and litigated cases brought by DOJ may be appealed to a U.S. Court of Appeals. Parties seeking review of a Court of Appeals decision may petition the U.S. Supreme Court to review the case. If a defendant violates a court’s decree, DOJ may seek to enforce it through contempt proceedings before the court.