

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

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

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

**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.**

**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**

Answer to Question 1:

The standard of patentability is prescribed in Section 2.1.(j) of the Patents Act 1970. The relevant section is reproduced below:

2.1.(j) "invention" means a new product or process involving an inventive step and capable of industrial application;

Section 2.1.(ja) and (ac) define what are inventive steps and industrial applicability as below:

2.1 (ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;

2.1.(ac) "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry;

It may be noted that the same yardstick is applied uniformly for all technologies. However, the patentability of an invention is further dependent on exclusions as embedded in Sections 3 and 4 of the Indian Patents Act which are reproduced herein below:

Section 3- **What are not inventions:** The following are not inventions within the meaning of the Act,—

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

*Explanation.*—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

.....

(h) a method of agriculture or horticulture;

(i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

(j) plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

(k) a mathematical or business method or a computer programme *per se* or algorithms;

(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(m) a mere scheme or rule or method of performing mental act or method of playing game;

(n) a presentation of information;

(o) topography of integrated circuits;

(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

#### Section 4: **Inventions relating to atomic energy not patentable**

No patent shall be granted in respect of an invention relating to atomic energy falling within sub-section (1) of section 20 of the [Atomic Energy Act, 1962 \(33 of 1962\)](#)

Source of Law: (Statutory Law).....Indian Patents Act 1970 and The Patents Rules 2003

**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?**

Answer to Question 2:

Section 48 of the Indian Patents Act provides the Rights accorded to the Patentee subject to the other provisions of the Act and conditions as specified in the Section 47 and other Sections of the Patents Act which are reproduced herein below:

Section 48:

- a) Where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;
- b) Where the subject matter of the patent is a process, the exclusive right to third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India.

**Response to the second and last portion of the question 2** i.e. “In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?” is as follows;

According to the Indian Patents Act ordinarily an application is published at the expiry of 18 months period calculated from the date of priority. However, the application can be published even before that period if the applicant requests for an early publication. In fact patent right will not be granted till the lapse of 6 months from the date of publication. [Please see Section 11A, Rules 24A, 24B and Rule 55(1A)].

The provisions of Sub-section 7 of Section 11-A of the Indian Patents Act prescribes the date from which the rights of the applicants are accrued, when the patent is granted, in the following language:

“On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application:

Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted”.

“Provided further that the rights of a patentee in respect of applications made under sub-section (2) of section 5 before the 1st day of January, 2005 shall accrue from the date of grant of the patent:

Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises”.

It may be noted that Section 5(2) was introduced in conformity with Article 78 of the TRIPS agreement and has now been deleted.

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

- Private and/or non-commercial use;
- Experimental use and/or scientific research;
- Preparation of medicines;
- Prior use;
- Use of articles on foreign vessels, aircrafts and land vehicles;
- Acts for obtaining regulatory approval from authorities;
- Exhaustion of patent rights;

\_ Compulsory licensing and/or government use;

\_ Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.3

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions". Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Answer to Question 3

a	Private and/or non-commercial use	YES, Section 47 (3)
b	Experimental use and/or scientific research	YES, Section 47 (3)
c	Preparation of medicines	NO EXPLICIT EXCEPTION
d	Prior use	YES, Section 11A(7)
e	Use of articles on foreign vessels, aircrafts and land vehicles	YES, Section-49
f	Acts for obtaining regulatory approval from authorities	YES, Section 107A (a)
g	Exhaustion of patent rights	YES, Section 107A (b)
h	Compulsory licensing	YES, Sections 83 to 94
i	Government use	YES, Sections 99 to 103
j	Exceptions and limitations related to farmers' and/or breeders' use of patented inventions	No such provisions in the Patents Act
k	Revocation of patents by the Central Government in the public interest if the patent or the mode in which it is used is found to be mischievous to the state	YES, Section 66
l	Revocation of patent or amendment of complete specification on directions from Government in cases relating to atomic energy	YES, Section 65
m	Revocation of the patent by the Central Government in the interest of Security of India	YES, Section 157A

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

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

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

**3** For example, in some countries where patent rights extend to propagated or multiplied material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do

**not constitute patent infringement. Similarly, in some countries, patent rights do not cover uses by breeders of patented biological material for the purpose of developing a new plant variety (see paragraphs 133 to 137 of document SCP/13/3).**

Answer to Question 4: Private or non-commercial use has been enshrined in the 'Act in various forms. Although not exactly similar to the examples given, such private and non-commercial uses are allowable for the purpose of research/teaching under Section 47(3) of the 'Act. Similarly non-commercial uses, e.g., public non-commercial uses are allowable under compulsory licenses under Section 92 of the Act. Further examples of non-commercial uses are examples of Government uses under Section 47 or under Section 100 of the Act.

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

Answer to Question 5

No case law.

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

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

Answer to Question 6

The policy objectives behind these provisions are mainly to preserve the public interest, e.g., the exclusive right conferred by a patent should not hinder the process of teaching or research (Section 47) or the patent right should not be an impediment for the Government to preserve the public health in case of any epidemic (Section 92) or should not prevent the Government from using the patent solely for its own purpose (Section 47) and importation of medicine or drug by the government for the purpose of distribution in any hospital ,dispensary or any other medical institution having regard to the public service rendered by them (section-47(4)).

**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):**

Answer to Question 7

No such definition in the Patents Act

**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):**

Answer to Question 8

Not applicable

**9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:**

Answer to Question 9

The provisions so far appear to be adequate.

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

Answer to Question 10

No challenge yet

### ***Section III: Experimental use and/or scientific research 4***

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

Answer to question 11: Contained in the Patents Act. Section 47(3) of the Act provides exemption to experimental use and/or scientific research.

Any machine or apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.(section 47(3))

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

Answer to Question 12

No case law is available.

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

**The objective is to promote research and development in the country as well as to ensure that patent rights must not impede higher education.**

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

Reply to question 13: As discussed previously, the public policy objective behind this exception is to ensure that patent rights should not hinder research and education in the country.

**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:**

Answer to Question 14: There is no such distinction in the 'Act.

**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):**

Answer to Question 15: No definitions are provided in the Patents Act.

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

**Experimentation and/or research should aim to:**

- determine how the patented invention works**
- determine the scope of the patented invention**

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

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

Answer to Question 16:

The exception as is provided in Section 47(3) for the purposes of experiment or research includes imparting instructions to pupils. No limitation on the scope of the experimentation and research.

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

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

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

Answer to Question 17

No limitation on the scope and extent of research and experimentation.

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

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

Answer to Question 18



As indicated above, there is no limitation of scope and extent of research and experimentation.

**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):**

Answer to Question 19

Law does not make any difference

**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):**

NO

**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:**

Answer to Question 21

At present they seem to be adequate

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

Answer to Question 22

Since the answer to question to 14 is ‘No’ these questions are not relevant.

#### ***Section IV: Preparation of medicines***

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

Answer to Question 23: Not Applicable

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

Answer to Question 24: No case law is available

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

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

Answer to Question 25: Not applicable

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

Answer to Question 26: Not applicable

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

Yes

No

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

Answer to Question 27: Not applicable

**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):**

Answer to Question 28: Not applicable

**29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:**

Answer to Question 29: Not applicable

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

Answer to Question 30: Not applicable

#### ***Section V: Prior use***

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

Answer to Question 31: Prior use amounts to anticipation as per Section 2.1.(l) of the Patents Act. The said section is quoted herein below:

(l) "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art;

An invention, if used before the date of priority lacks in novelty and is not allowable under the 'Act. However, there are certain exceptions to this Rule.

Prior Secret trial or secret use by third parties are not considered for the purposes of anticipation or obviousness under Sections 25(5) and Sections 64 of the Act in proceedings for revocations.

Similarly prior use by the patentee or applicant for patent, or any person with Or without his consent shall not be deemed to be falling within anticipation subject to certain conditions. Chapter VI of the 'Act provides such exceptions and some of the relevant Sections are quoted herein below:

#### “Section 29

##### Anticipation by previous publication

Anticipation by previous publication.—

(1) An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that the invention was published in a specification filed in pursuance of an application for a patent made in India and dated before the 1st day of January, 1912.

(2) Subject as hereinafter provided, an invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that the invention was published before the priority date of the relevant claim of the specification, if the patentee or the applicant for the patent proves—

(a) that the matter published was obtained from him, or (where he is not himself the true and first inventor) from any person from whom he derives title, and was published without his consent or the consent of any such person; and

(b) where the patentee or the applicant for the patent or any person from whom he derives title learned of the publication before the date of the application for the patent, or, in the case of a convention application, before the date of the application for protection in a convention country, that the application or the application in the convention country, as the case may be, was made as soon as reasonably practicable thereafter:

Provided that this sub-section shall not apply if the invention was before the priority date of the claim commercially worked in India, otherwise than for the purpose of reasonable trial, either by the patentee or the applicant for the patent or any person from whom he derives title or by any other person with the consent of the patentee or the applicant for the patent or any person from whom he derives title.

(3) Where a complete specification is filed in pursuance of an application for a patent made by a person being the true and first inventor or deriving title from him, an invention claimed in that specification shall not be deemed to have been anticipated by reason only of any other application for a patent in respect of the same invention made in contravention of the rights of that person, or by reason only that after the date of filing of that other application the invention was used or published, without the consent of that person, by the applicant in respect of that other application, or by any other person in consequence of any disclosure of any invention by that applicant.

#### Section 30

##### Anticipation by previous communication to Government

An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only of the communication of the invention to the Government or to any person authorized by the Government to investigate the invention or its merits, or of anything done, in consequence of such a communication, for the purpose of the investigation.

Section 31:

An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only of—

(a) the display of the invention with the consent of the true and first inventor or a person deriving title from him at an industrial or other exhibition to which the provisions of this section have been extended by the Central Government by notification in the Official Gazette, or the use thereof with his consent for the purpose of such an exhibition in the place where it is held; or

(b) the publication of any description of the invention in consequence of the display or use of the invention at any such exhibition as aforesaid; or

(c) the use of the invention, after it has been displayed or used at any such exhibition as aforesaid and during the period of the exhibition, by any person without the consent of the true and first inventor or a person deriving title from him; or

(d) the description of the invention in a paper read by the true and first inventor before a learned society or published with his consent in the transactions of such a society,

if the application for the patent is made by the true and first inventor or a person deriving title from him not later than twelve months after the opening of the exhibition or the reading or publication of the paper, as the case may be

Section 32 Anticipation by Public working.

An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that at any time within one year before the priority date of the relevant claim of the specification, the invention was publicly worked in India -

a. by the patentee or applicant for the patent or any person from whom he derives title; or

b. by any other person with the consent of the patentee or applicant for the patent or any person from whom he derives title, if the working was effected for the purpose of reasonable trial only and if it was reasonably necessary, having regard to the nature of the invention, that the working for that purpose should be effected in public”.

Still further it may be noted that under proviso of Section 11A (7) he patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no

infringement proceedings shall be instituted against such enterprises. [Please see above, under the question no. 2].

Prior Use by the Government under Section -100(2)-

Where an invention has, before the priority date of the relevant claim of the complete specification, been duly recorded in a document or tested or tried, by or on behalf of the Government or a Government undertaking, otherwise than in consequence of communication of the invention directly or indirectly by the patentee or by a person from whom he derives title, any use of the invention by the Central Government or any person authorized in writing by it for the purpose of the Government may be made free of any royalty or other remuneration to the patentee.

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

Answer to Question 32: No case law is available.

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

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

Answer to question 33: The public policy objectives are (a) to provide a reasonable grace period to the applicant from his disclosure or reasonable trial etc. to the date of filing (b) to provide immunity to the applicant from the unlawful disclosure by a third party (c) to provide immunity to the applicant when he discloses his inventions to the Government and (d) power of the central government in case prior use .

**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):**

Answer to Question 34: No quantitative and qualitative limitations of prior use is defined.

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

Answer to Question 35: For the answers with respect to the remuneration paid by the Government, please see below. For the situations under proviso of Section 11A(7), patent-holder shall only be entitled to receive reasonable royalty [see above].

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

Yes  
 No

Answer to Question 36: 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?**

Yes

No

**If yes, please explain what those conditions are:**

Answer to Question 37: Not applicable

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

Yes

No

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

Answer to Question 38: Under Section 62 of the 'Act, no suit or other proceedings shall be commenced in respect of an infringement of a patent committed between the date on which the patent ceased to have effect and the date of publication of the application for the restored patent.

**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):**

Answer to Question 39: No

**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:**

Answer to Question 40: No amendments are required.

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

Answer to Question 41: No challenges have been encountered.

***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):**

Answer to Question 42:

Section 49 of the Indian Patents Act:

49. Patents rights not infringed when used on foreign vessels, etc., temporarily or accidentally in India

(1) Where a vessel or aircraft registered in a foreign country or a land vehicle owned by a person ordinarily resident in such country comes into India (including the territorial waters thereof) temporarily or accidentally only, the rights conferred by a patent for an invention shall not be deemed to be infringed by the use of the invention -

a. in the body of the vessel or in the machinery, tackle, apparatus or other accessories thereof, so far as the invention is used on board the vessel and for its actual needs only; or

b. in the construction or working of the aircraft or land vehicle or of the accessories thereof, as the case may be.

(2) This section shall not extend to vessels, aircraft or land vehicles owned by persons ordinarily resident in a foreign country the laws of which do not confer corresponding rights with respect to the use of inventions in vessels, air crafts or land vehicles owned by persons ordinarily resident in India while in the ports or within the territorial waters of that foreign country or otherwise within the jurisdiction of its courts.

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

Answer to Question 43: No case law is available.

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

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

Answer to question 44: This exception is allowed to enable the entry of the foreign vessels, aircrafts and land-vehicles in the Indian territory so that patent rights do not inhibit movements of such transports.

**45. The exception applies in relation to:**

Vessels

Aircrafts

Land Vehicles

Spacecraft

Answer to Question 45: Vessels, Aircrafts and Land vehicles

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

Answer to Question 46: Yes, the words "temporarily or accidentally only" are used in the statute. No definitions for the said words are provided.

**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):**

Answer to Question 47:

This exception is applicable to patents for inventions :

- a. in the body of the vessel or in the machinery, tackle, apparatus or other accessories thereof, so far as the invention is used on board the vessel and for its actual needs only; or
- b. in the construction or working of the aircraft or land vehicle or of the accessories thereof, as the case may be.

**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):**

Answer to Question 48:

Where there is no reciprocity then use of invention on foreign vessels shall be treated as infringement. Please refer Section 49(2) as quoted above.

**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:**

Answer to Question 49: Yes

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

Answer to Question 50: No challenges have been encountered so far.

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

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

Answer to Question 51:

Exception for obtaining regulatory approval is embedded in Section 107A (a). The relevant provision is quoted herein below:

Section 107A

Certain acts not to be considered as infringement

For the purposes of this Act,—

(a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;

....

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



Answer to Question 52: No case law is available

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

.The policy objective is that the manufacturing of such products should not be delayed due to the time taken for obtaining marketing approval.

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

Answer to Question 53: The policy objective behind this provision is enable the submission of reports to a regulatory authority.

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

Answer to Question 54: No limitation.

**55. The exception covers the regulatory approval of:**

any products

certain products. Please describe which products:

Answer to Question 55: No limitation

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

Making

Using

Selling

Offering for sale

Import

Export

Other. Please specify:

Answer to Question 56: Act of making, constructing, using, selling or importing a patented invention

**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):**

Answer to Question 57: Not applicable.

**58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:**

Answer to Question 58: Adequate.

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

Answer to Question 59: Not applicable.

**Section VIII: Exhaustion of patent rights**

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

- 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:**

Answer to Question 60: International exhaustion is explicitly mentioned in the 'Act as stipulated in Section 107A of the 'Act as quoted herein below:

Section 107A  
Certain acts not to be considered as infringement

For the purposes of this Act,—

.....

(b) importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as a infringement of patent rights.

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

**Please explain:**

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

Answer to Question 61: The policy objective is to allow importation of patented products in the country from such markets where the product has been placed in duly authorized manner.

**62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?**

- Yes
- No
- Uncertain

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

Answer to Question 62: No

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

Answer to Question 63: 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:**

Answer to Question 64: No challenges have been encountered so far.

***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):**

Answer to Question 65:

Compulsory Licensing is governed by Chapter XVI, Sections 82 to Section 94 of the 'Act.

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

Answer to Question 66: Not applicable.

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

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

Answer to Question 67: Compulsory Licenses can be granted to redress all the situations as enumerated in the question and other situations as well, e.g.:

- a) Non-working or insufficient working of the patented invention
- b) Refusal to grant licenses on reasonable terms
- c) Anti-competitive practice
- d) Public health
- d) National emergency and/or extreme urgency
- e) Public non-commercial use
- f) Dependent patents

- g) Reasonable requirement of the public not satisfied
- h) The patented invention is not available to the public at a reasonably affordable price
- i) To export a patented medicine to a country having no-manufacturing capacity or inadequate manufacturing capacity.

Broadly speaking Compulsory Licenses are granted under four situations:

- a. In the event the reasonable requirement of the public is not met or patented invention is not available to the public at a reasonably affordable price or the patented invention is not worked in India, the compulsory licenses can be granted by the Controller of Patents any time after the period of three years from the grant of the patent [**Section 84**]
- b. In circumstances of national emergency, circumstances of extreme urgency or in case of public non-commercial use at any time after the grant of the patent, the Central Government may make a declaration in the official gazette that compulsory license can be granted for certain patents. Thereafter any person interested may make application to the controller of patents for the grant of compulsory license under such patents. [Section 92].
- c. In continuation to the aforesaid provision, if a circumstance of national emergency or extreme urgency or in a case of public non-commercial use arise due to the epidemics like HIV/AIDS, TB, malaria or other such epidemics, the compulsory license can be granted by the Controller of Patents to any person interested any time after the grant of the patent pursuant to the notification by the Central Government. Under this category, however, the procedures of notification and opposition will not apply and the Controller shall, as soon as may be practicable, inform the patentee of such non-application [Section 92].
- d. Pursuant to DOHA declaration on TRIPs and Public Health, the provision has been incorporated in the Indian Patents Act to grant a compulsory licence for exporting the patented medicine to the countries with no-manufacturing capacity or insufficient manufacturing capacity in the pharmaceutical sector to address the public health problems of that country with respect to the concerned pharmaceutical products [Section 92A].

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

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

Answer to Question 68: The public policy objectives behind the grant of compulsory licensing is stipulated under Section 83 of the 'Act. Section 83 is quoted below:

General principles applicable to working of patented inventions

Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;—

- a. that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
- b. that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- c. that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
- d. that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
- e. that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
- f. that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
- g. that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

**69. If the applicable law provides for the grant of compulsory licenses on the ground of “nonworking” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):**

Answer to Question 69: “Nonworking” or “insufficient working” are not defined in the 'Act.

**The Act refers to following terms:**

- a) the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- b) the patented invention is not available to the public at a reasonably affordable prices, or

c) the patented invention is not worked in the territory of India.

**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):**

Answer to Question 70:

Yes. One of the rights of the patentee as specified in the Section 48 of the Indian Patents Act is ‘IMPORT” of the patented product or the product obtained by the patented process. But for the grant of compulsory license the mere importation of the patented product or the product obtained by a patented process that either prevents or hinders the actual working in the territory of India on a commercial scale can be treated as a ground that the reasonable requirements of the public have not been satisfied.

**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?**

Answer to Question 71: Yes. At any time after the expiration of 3 years from the date of grant of the patent.

**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”?**

Answer to Question 72: The answer lies in the provisions as stipulated in the Section 86 of the Indian Patents Act. If the patentee justifies his inaction by legitimate reasons, then the Controller of patents may adjourn the decision to such period till the patentee can not justify his inaction. Section 86 is quoted as herein below:

Section-86 -Power of Controller to adjourn applications for compulsory licenses, etc., in certain cases  
(1) Where an application under section 84 or section 85 as the case may be, is made on the grounds that the patented invention has not been worked in the territory of India or on the ground mentioned in clause (d) of sub-section 7 of the Section 84 [if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable] and the Controller is satisfied that the time which has elapsed since the grant of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable, he may, by order adjourn the further hearing of the application for

such period not exceeding twelve months in the aggregate as appears to him to be sufficient for the invention to be so worked:

Provided that the in any case where the patentee establishes that the reason why a patented invention could not be worked as aforesaid before the date of the application was due to any State or Central Act or any rule or regulation made there under or any order of the Government imposed otherwise than by way of a condition for the working of the invention in the territory of India or for the disposal of the patented articles or of the articles made by the process or by the use of the patented plant, machinery, or apparatus, then, the period of adjournment ordered under this sub-section shall be reckoned from the date on which the period during which the working of the invention was prevented by such Act, rule or regulation or order of Government as computed from the date of the application, expires.

(2) No adjournment under sub-section (1) shall be ordered unless the Controller is satisfied that the patentee has taken with promptitude adequate or reasonable steps to start the working of the invention in India on a commercial scale and to an adequate extent.

**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):**

Answer to Question 73: Definition for “reasonable period” is provided under explanation of Clause (iv) of Sub-section 6 of Section 84 of the Indian Patents Act. According to this provision the “reasonable period” shall be construed as a period not ordinarily exceeding a period of 6 months.

Clause (iv) of Sub-section 6 of Section 84:

“As to whether the applicant [compulsory license seeker] has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit.

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or an establishment of a ground of anti-competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.”

No explanation is being provided for the term “reasonable terms and conditions”.

**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):**

Answer to Question 74: Under the provisions of Clauses (b) & (c) of Sub-section 7 of Section 84 of the Indian Patents Act the anti-competitive practices by the patentee has been stated as, inter alia, the grounds for compulsory license.

Section 84 (7) “For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied”

.....

Clause (b) of Sub-section 7 of Section 84:

“If, by reason of conditions imposed by the patentee upon the grant of licenses under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced”;

Clause (c) of Sub-section 7 of Section 84:

“If the patentee imposes a condition upon the grant of licenses under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing”;

The above criteria, if established as being anti-competitive practice by the patentee then it is understood that the reasonable requirements of the public is deemed not to have been satisfied and also on understanding of the explanation as provided under Clause (iv) of Sub-section 6 of Section 84, a compulsory license can be granted. [Please see above].

**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:**

Answer to Question 75: Section 91 of the Indian Patents Act deals with the grant of licenses of dependent patents.

“Section 91: Licensing of related patents

(1) Notwithstanding anything contained in the other provisions of this Chapter, at any time after the grant of a patent, any person who has the right to work any other patented invention either as patentee or as licensee thereof, exclusive or otherwise, may apply to the Controller for the grant of a license of the first mentioned patent on the ground that he is prevented or hindered without such license from working the other invention efficiently or to the best advantage possible.

(2) No order under sub-section (1) shall be made unless the Controller is satisfied -

(i) that the applicant is able and willing to grant, or procure the grant to the patentee and his licensees if they so desire, of a license in respect of the other invention on reasonable terms; and

(ii) that the other invention has made a substantial contribution to the establishment or development of commercial or industrial activities in India.

(3) When the Controller is satisfied that the conditions mentioned in sub-section (1) have been established by the applicant, he may make an order on such terms as he thinks fit granting a license under the first mentioned patent and a similar order under the other patent if so requested by the proprietor of the first mentioned patent or his licensee

Provided that the license granted by the Controller shall be non-assignable except with the assignment of the respective patents.

(4) The provisions of sections 87, 88, 89 and 90 shall apply to licenses granted under this section as they apply to licenses granted under section 84”.



When the license is granted under a patent and the license cannot be worked without some other patent held by same patentee the Controller by order can grant license with respect to the said other patents held by the same patentee. This provision has been laid in Sub-section 3 of Section 88 of the Indian Patents Act.

“Subsection 3 of Section 88:

Where two or more patents are held by the same patentee and an applicant for a compulsory license establishes that the reasonable requirements of the public have not been satisfied that the applicant cannot efficiently or satisfactorily work the license granted to him under those patents without infringing the other patents held by the patentee and if those patents involve important technical advancement of considerable economic significance in relation to the other patents, he may, by order, direct the grant of a license in respect of the other patents also to enable the license to work the patent or patents in regard to which a license is granted under section 84”.

**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:**

Answer to Question 76: YES

There is a general policy provided in the Indian Patents Act with respect to the remuneration to be paid by the beneficiary of the compulsory license to the patentee.

Clause (i) of Sub-section 1 of Section 90:

“In settling the terms and conditions of a license under section 84, the Controller shall endeavor to secure-

(i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors”;

[In this connection please note that under the powers of Central Government [Section 100 of the Indian Patents Act] to use inventions for the purposes of Government use between the date of filing an application for patent and any time during the patent in force, if the Government decided to use the said invention either by the Government or by any person authorized by the Government to do so then the royalty to be paid to the patentee is not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent].

**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:**

Answer to Question 77:

There is no explicit definition of these phrases in the Act. However sub-section 3 of Section 92 of the 'Act describes certain situations of exigency under which Compulsory Licensing can be applied in a

quicker manner bypassing the detailed procedure of notifying the patentee or inviting oppositions as provided under section 87 of the 'Act.

Sub-section 3 of Section 92:

“Notwithstanding anything contained in subsection (2) [i.e. the Controller is exempted to follow the procedures as laid down in the sections 83,87,88,89 and 90], where the Controller is satisfied on consideration of the application referred to in clause (i) of Sub-section (1) that is necessary in-

- (i) a circumstance of national emergency; or
- (ii) a circumstance of extreme urgency; or
- (iii) a case of public non-commercial use;

which may arise or is required, as the case may be, including public health crises, relating to Acquired Immuno Deficiency Syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of license under this section;

provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87”.

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

Answer to Question 78: Under the Patents Act, (before the recent amendments) only in few cases compulsory licenses were issued (4 in the mechanical field, one in chemicals: catalyst). After the amendment took place (in 1999, 2002 and 2005) only one Compulsory License has been granted for a patent related to an Anti-cancer medicine, the said decision has been challenged before the Court.

**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:**

Answer to Question 79: The legal frame work is considered to be adequate to meet the objectives

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

Answer to Question 80: No challenges have been encountered so far.

*Government use*

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

Answer to Question 81: Chapter XVII of the Indian Patents Act is related to the use of inventions for the purposes of Government and acquisition of inventions by Central Government. It comprises 5 sections starting from 99 and ending with 103.

- 1) Section 99: Meaning of use of invention for purposes of Government [2 subsections]
- 2) Section 100: Power of Central Government to use inventions for purposes of Government. [ 7 subsections]
- 3) Section 101: Rights of third parties in respect of use of invention for purposes of Government [ 3 subsections]
- 4) Section 102: Acquisition of inventions and patents by the Central Government [ 3 subsections]
- 5) Section 103: Reference to High Court of disputes as to use for purposes of Government

The exception is provided in sub-section 3 of section 99 which states;

Section 99

“Meaning of use of invention for purposes of Government

- (1) For the purposes of this Chapter, an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking.
- (2) [omitted]

- (1) Nothing contained in this chapter shall apply in respect of any such importation, making or using of any machine, apparatus or other article or of any such using of any process or of any such importation, using or distribution of any medicine or drug, as may be made by virtue of one or more of the conditions specified in Section 47”

Section 47: Grant of Patents to the subject to certain conditions:

“The grant of a patent under this Act shall be subject to the condition that:-

- 1) Any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the Government for the purpose merely of its own use;
- 2) Any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use;
- 3) Any machine or apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils; and
- 4) In the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette

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

Answer to Question 82: No case law is available.

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

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

Answer to Question 83: Under Chapter XVII (read with Section 47) there is no limitations with respect to the use by Government.

**84. (a) What are the public policy objectives for providing government use in your country?  
(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:**

Answer to Question 84: To enable the Government to use any invention whenever it is so required.

**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:**

Answer to Question 85:

These phrases are not defined in the Act. Also please see the answer with respect these phrases under Compulsory Licensing. However, it may be noted that in case of Government use the patentee is notified of such use, excepting in case “national emergency” or “circumstances of extreme urgency” or “public non-commercial use”. [Please see Sub-section (5) of Section 100].

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

Answer to Question 86: None

**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:**

Answer to Question 87: Yes. No amendments are required.

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

Answer to Question 88: No challenges have been encountered so far

**Question numbers from 89 to 100 are as follows:**

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

*For the following questions numbering 89 to 100, no comments are possible through the provisions of the Indian Patents Act. Farmer's right and/or breeder's right do not fall within the Patents Act 1970. It may be reckoned that the Patents Act excludes patenting of all forms of plants and animals including seeds (excluding micro organisms made through human intervention)*

***Farmers' use of patented inventions***

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

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

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

**(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):**

.

**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:**

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

***Breeders' use of patented inventions***

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

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

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

**(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):**

**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:**

**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:**

The subject matter related to questions starting from 89 to 100 is not the subject matter of the Indian Patents Act. Hence no answers can be provided through the provisions of the Indian Patent law. However India follows the sui generis system as far as the plant breeder rights are concerned.

THE PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS ACT, 2001, , covers the subject matter of the questions of 89 to 100.

***Section XI: Other Exceptions and Limitations***

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

a	Revocation of patents by the Central Government in the public interest if the patent or the mode in which it is used is found to be mischievous to the state	Section 66
b	Revocation of patent or amendment of complete specification on directions from Government in cases relating to atomic energy	Section 65
c	Revocation of the patent by the Central Government in the interest of Security of India	Section 157A
d	NO SUIT FOR INFRINGEMENT FOR A PERIOD BETWEEN WHEN PATENT IS LAPED DUE TO NON PAYMENT OF FEE AND DATE OF PUBLICATION OF APPLICATION RESTORATION	Section 62(2)

**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):**

**(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:**

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

**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?):**

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

The aforesaid Sections of the 'Act read as follows:

“Section 65

Revocation of patent or amendment of complete specification on directions from Government in cases relating to atomic energy

(1) Where at any time after grant of a patent, the Central Government is satisfied that a patent is for an invention relating to atomic energy for which no patent can be granted under sub-section (1) of section 20 of the Atomic Energy Act, 1962 (33 of 1962), it may direct the Controller to revoke the patent, and thereupon the Controller, after giving notice, to the patentee and every other person whose name has been entered in the register as having an interest in the patent, and after giving them an opportunity of being heard, may revoke the patent.

(2) In any proceedings under sub-section (1), the Controller may allow the patentee to amend the complete specification in such manner as he considers necessary instead of revoking the patent.

Section 66

Revocation of patent in public interest

Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.

Section 157A

Protection of security of India

Notwithstanding anything contained in this Act, the Central Government shall:-

(a) not disclose any information relating to any patentable invention or any application relating to the grant of patent under this Act, which it considers prejudicial to the interest of security of India;

(b) take any action including the revocation of any patent which considers necessary in the interest of the security of India by issue of a notification in the Official Gazette to that effect.

Explanation.- For the purposes of this section, the expression "security of India" includes any action necessary for the security of India which,

(i) relates to fissionable materials or the materials from which they are derived; or

(ii) relates to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment; or

(iii) is taken in time of war or other emergency in international relations”

The policy objectives behind these provisions is to revoke patents which are against the public interest or are mischievous to the state or the revocation of which is essential in the interest of India.

SECTION -62(2) No suit or other proceedings shall be commenced or prosecuted in respect of an infringement of a patent committed between the date on which patent has ceased to have effect and date of publication of the application for restoration of patent.

Policy objective is to protect the person who in good faith believing the patent as ceased , has used the invention during the period as indicated

**103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:**

Section 3 THE COMPETITION ACT, 2002 enumerates the Anti-competitive agreements prescribes that:

However, Sub-section (5) reads as:

“Nothing contained in this section shall restrict—

(i) the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him under—

(a) the Copyright Act, 1957 (14 of 1957);

(b) the Patents Act, 1970 (39 of 1970);

(c) the Trade and Merchandise Marks Act, 1958 (43 of 1958) or the Trade Marks Act, 1999 (47 of 1999);

(d) the Geographical Indications of Goods (Registration and Protection) Act, 1999 (48 of 1999);

(e) the Designs Act, 2000 (16 of 2000);

(f) the Semi-conductor Integrated Circuits Layout-Design Act, 2000 (37 of 2000)”;



The public policy objectives for these exceptions is that the holders of the respective IPRs shall enjoy their rights as long as the conditions imposed by them are not unreasonable and are detrimental to competition .

In addition to the anti-competitive practices as said in the context of the Compulsory Licensing, the following Sections need special mentions as they deal with anti-competitive practices:

“Section 140

Avoidance of certain restrictive conditions

(1) It shall not be lawful to insert—

(i) in any contract for or in relation to the sale or lease of a patented article or an article made by a patented process; or

(ii) in licence to manufacture or use a patented article; or

(iii) in a licence to work any process protected by a patent, a condition the effect of which may be—

to require the purchaser, lessee, or licensee to acquire from the vendor, lessor, or licensor or his nominees, or to prohibit from acquiring or to restrict in any manner or to any extent his right to acquire from any person or to prohibit him from acquiring except from the vendor, lessor, or licensor or his nominees any article other than the patented article or an article other than that made by the patented process; or

to prohibit the purchaser, lessee or licensee from using or to restrict in any manner or to any extent the right of the purchaser, lessee or licensee, to use an article other than the patented article or an article other than that made by the patented process, which is not supplied by the vendor, lessor or licensor or his nominee; or to prohibit the purchaser, lessee or licensee from using or to restrict in any manner or to any extent the right of the purchaser, lessee or licensee to use any process other than the patented process, to provide exclusive grant back, prevention to challenges to validity of Patent & Coercive package licensing, and any such condition shall be void.

( 2) A condition of the nature referred to in clause (a) or clause (b) or clause (c) of sub-section (1) shall not cease to be a condition falling within that sub-section merely by reason of the fact that the agreement containing it has been entered into separately, whether before or after the contract relating to the sale, lease or licence of the patented article or process.

(3) In proceedings against any person for the infringement of a patent, it shall be a defence to prove that at the time of the infringement there was in force a contract relating to the patent and containing a condition declared unlawful by this section:

Provided that this sub-section shall not apply if the plaintiff is not a party to the contract and proves to the satisfaction of the court that the restrictive condition was inserted in the contract without his knowledge and consent, express or implied.

(4) Nothing in this section shall—

affect a condition in a contract by which a person is prohibited from selling goods other than those of a particular person;

validate a contract which, but for this section, would be invalid;

affect a condition in a contract for the lease of, or licence to use a patented article, by which the lessor or licensor reserves to himself or his nominee the right to supply such new parts of the patented article as may be required or to put or keep it in repair.

(5) [Omitted]

## Section 141

### Determination of certain contracts

(1) Any contract for the sale or lease of a patented article or for licence to manufacture, use or work a patented article or process, or relating to any such sale, lease or licence, may at any time after the patent or all the patents by which the article or process was protected at the time of the making of the contract has or have ceased to be in force, and notwithstanding anything to the contrary in the contract or in any other contract, be determined by the purchaser, lessee, or licensee, as the case may be, of the patent on giving three months notice in writing to the other party.

(2) The provisions of this section shall be without prejudice to any right of determining a contract exercisable apart from this section”.

[End of document]