

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

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

Country: **People's Republic of China**  
Office: **State Intellectual Property Office of China**

Person to be contacted:

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**Section I: General**

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

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

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

In accordance with the provisions of the Patent Law of China, to be granted a patent, an invention must be novel, creative and of practical use. The criteria on patentability should not vary for different technical fields.

Article 22 of the Patent Law provides that:

"Inventions and utility models for which patent rights are to be granted shall be ones which are novel, creative and of practical use.

"Novelty means that the invention or utility model concerned is not an existing technology; no patent application is filed by any unit or individual

for any identical invention or utility model with the patent administration department under the State Council before the date of application for patent right, and no identical invention or utility model is recorded in the patent application documents or the patent documentations which are published or announced after the date of application.

"Creativity means that, compared with the existing technologies, the invention possesses prominent substantive features and indicates remarkable advancements, and the utility model possesses substantive features and indicates advancements.

"Practical use means that the said invention or utility model can be used for production or be utilized, and may produce positive results."

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.<sup>1</sup>

Article 5 of the Patent Law provides that patent shall not be granted for inventions or creations that violate the law or social ethics, or harm public interests; patent rights shall not be granted for inventions that are accomplished by relying on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations.

Article 25 of the Patent Law provides that patent rights shall not be granted for any of the following:

- (1) scientific discoveries;
- (2) rules and methods for intellectual activities;
- (3) methods for the diagnosis or treatment of diseases;
- (4) animal or plant varieties;
- (5) substances obtained by means of nuclear transformation; and
- (6) designs that are mainly used for marking the pattern, color or the combination of the two of prints. (Note: three types of patent are granted under the Patent Law of China, i.e. inventions, utility models and designs)

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<sup>1</sup> This question does not imply that the topic of exclusions from patentability is dealt with in this question exhaustively.

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?]

In accordance with Article 11 of the Patent Law, "the exclusive rights granted with a patent" means that after the patent right is granted for an invention or a utility model, unless otherwise provided for in this Law, no unit or individual may exploit the patent without permission of the patentee, i.e., it or he may not, for production or business purposes, manufacture, use, offer to sell, sell, or import the patented products, use the patented method, or use, offer to sell, sell or import the products that are developed directly through the use of the patented method.

Under the Patent Law of China, all published patent applications are under provisional protection. In particular, Article 13 of the Patent Law provides that after the application for an invention patent is published, the applicant may require the unit or individual that exploits the said patent to pay an appropriate amount of royalties.

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;<sup>2</sup>
  - 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.<sup>3</sup>

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".

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<sup>2</sup> For example, extemporaneous preparation of prescribed medicines in pharmacies.

<sup>3</sup> 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).

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

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

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

Article 11 of the Patent Law grants patent right holders the right to prohibit others from implementing their inventions or creations for production or business purposes. However, manufacturing, using, offering to sell, selling, or importing the patented products, which are not for production or business purposes, does not constitute implementation of the patent, nor does it require to acquire authorization by the patent right holders.

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

No.

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

The patent system allows right holders to get full economic returns by granting them the exclusive rights to the implementation of their inventions or creations, thus achieving the objectives of encouraging inventions or creations. The patent system also aims to promote the application of inventions or creations, and to advance the technological progress and social and economic development. Therefore, while encouraging innovation, the patent system also needs to ensure the adequate balance between right holders and the legitimate interests of the public at large. Personal or non-commercial use does not affect the economic interests of neither the right holders nor the public at large, so one should not allow right holders to enjoy absolute exclusive ownership. If any acts that involve manufacturing, using, offering to sell, selling, or importing patented technologies without the authorization by the right holders are considered patent infringement, it would make the patent coverage excessively large, thus interrupting the normal activities of the public at large, and is not conducive to the reasonable balance between the rights and interests of the creators of technological knowledge and those of the users, nor to the promotion of the economic development or the well beings of the entire society.

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

Such exceptions had already been expressly provided for in the Patent Law of China that entered into force on April 1, 1985. Up to now, the Patent Law has been revised for three times, and there has been no change to the provision under Article 11 that the exclusive right granted by patent only involves acts for production or business purposes.

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

No definitions have been given in China's Patent Law or Regulations to "non-commercial", "commercial" or "private", nor to "for production or business purposes" under Article 11 of the Patent Law. It is generally understood, however, that "for production or business purposes" means for the purposes of industrial or agricultural production, or for commercial purposes. It has a wide connotation, and has nothing to do with being profitable or not, nor with the nature of the actor, i.e. whether it is a profitable or non-profitable entity.

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

No.

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

Yes.

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

No.

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

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

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

Article 69 of the Patent Law provides that it shall not be deemed to be infringing the patent right if any person uses the relevant patent exclusively for the purpose of scientific research and experimentation.

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

No.

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

The patent system must balance the rights of the patent right holders and the interest of the users of patented technologies and the public at large so as to maximize its social benefits. Scientific and technological innovations are always carried out on the basis of prior art. If use of relevant patents for scientific research and experimental purposes would be only possible with prior consent by the patent right holders, it may hinder the research and development process, and would thus not be conducive to scientific and technological progress, and contrary to the legislative purpose of patent laws.

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

Such exceptions had already been expressly provided for in the Patent Law of China that entered into force on April 1, 1985. Up to now, the Patent Law has been revised for three times, and this exception has never been changed.

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:

The application of this exception has nothing to do with the nature of the organization. If what an organization engaged in production and business does is just to carry out research and experiment on the patented technology itself, one could apply this exception, and consider such acts as not infringing the patent. But if such organization uses a patented technology for other projects of scientific research, it would not fall into the scope of this exception, and would constitute patent infringement.

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

No definition has been given in China's Patent Law directly to "scientific research".

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

Experimentation and/or research should aim to:

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

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):

**No.**

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

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

**No.**

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:]

Yes.

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

No.

**Section IV: Preparation of medicines**

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

In China, medical prescriptions, doctor's make up of prescriptions and the preparation of such make up are not considered as being industrially applicable, and thus not patentable. China's Patent Law or its Regulations do not provide for the make up of the prescriptions to be an exception to patent protection.

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

No.

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

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.....

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

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

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

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):

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.....  
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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):

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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:

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30. 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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.....  
.....

**Section V: Prior use**

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

Article 69 of the Patent Law provides that the following shall not be deemed to be patent right infringement

(2) before the date of patent application, any other person has already manufactured identical products, used identical method or has made necessary preparations for the manufacture or use and continues to manufacture the products or use the method within the original scope.

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

No.

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

The purpose of the Patent Law to provide for such an exception is to balance the rights of right holders and the legitimate interests of third

parties. Such limitation could help avoid unfairness that exists in real life, arising from the fact that the entities or individuals who have invested human and material resources in the creation of the invention are not able to exploit their own intellectual achievements just because they have not filed any patent applications before hand. It is to be noted, however, that the party who enjoys such right of prior use can only continue his production and exploitation within the original scope, and any production or exploitation beyond that scope would constitute patent infringement.

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

Such exceptions had already been expressly provided for in the Patent Law of China that entered into force on April 1, 1985. Up to now, the Patent Law has been revised for three times, and this exception has never been changed.

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

"Prior use" means the manufacture of the identical products and the use of identical method, or having made necessary preparations for such manufacture and use, prior to the filing date.

There are no quantitative limitations on the manufacture or use prior to the filing date. If the actual output is below that expected for manufacture, the quantity produced with the existing equipment is considered as within the original scope. Continued manufacture or use must be kept within this original scope.

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

No remuneration is to be paid to the patentee provided that continuous use is within the existing scale.

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

- Yes  
 No

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

- Yes
- No

If yes, please explain what those conditions are:

There are limitations on the assignment (including transfer and succession) of prior user's right. The prior user's right can only be assigned together with the enterprise that manufactures identical products or uses identical manufacturing method, or together with the part that involves the manufacturing of identical products or the use of identical manufacturing method, or together with the enterprise or a part of it that is supposed to engage in such production or use.

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:

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.....  
.....

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):

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:

Yes.

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

No.

**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):

Article 69 of the Patent Law provides that the following shall not be deemed to be patent right infringement□

(3) with respect to any foreign means of transportation that temporarily passes through the territory, territorial waters, or territorial airspace of China, the relevant patent is used in the devices and installations for its own needs, in accordance with the agreement concluded between the country it belong to and China, or in accordance with any international treaty to which both countries have acceded, or on the principle of mutual benefit.

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

No.

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

This limitation to patent is necessary to ensure free international transportation, and is in conformity with international practices and with the relevant provisions in the Paris Convention.

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

Such exceptions had already been expressly provided for in the Patent Law of China that entered into force on April 1, 1985. Up to now, the Patent Law has been revised for three times, and this exception has never been changed.

45. The exception applies in relation to:

- Vessels
- Aircrafts
- Land Vehicles
- Spacecraft

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

The applicable law has applied the term of "temporarily".

Article 69 of the Patent Law provides that such exception applies only to any foreign means of transportation that temporarily passes through the territory, territorial waters, or territorial airspace of China. Temporary passes imply the fact that such means of transportation is not operating in China on a permanent basis. They include provisional entries and accidental passes. Provisional entries may include entries on a regular basis, whereas accidental passes refer to passing through China's territory due to special circumstances, such as ships entering China's harbor to avoid a storm, or planes' forced landing at China's airport due to bad weather conditions.

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):

Yes. Such exceptional protection applies only to vessels that use relevant patent in their devices and installation for their own needs. The objective of this provision is to maintain the freedom in international transportation. Therefore, the right to use relevant patent is limited to the needs of the vessel itself, i.e. limited to acts necessary for the function of the vessel. The use of the patent under this provision covers the use of patented products or patented methods, but not the manufacture, offering to sell, or importation of patented products.

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):

No.

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

Yes.

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

No.

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

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

Article 69 of the Patent Law provides that the following shall not be deemed to be patent right infringement

(5) any person who produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or any third party who imports patented drugs or patented medical apparatus and instruments especially for that person.

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

No.

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

Drugs or medical apparatus and instruments are importantly related to public health, for which reason their circulation into the markets is under vigorous and long administrative examination and approving procedures in all countries. In order to pass such examination and approving procedures, manufacturers need to collect data and other information necessary for the examination and approval by conducting activities such as research, analysis and clinical experiment. Any enterprise (other than the patentee), which is engaged in imitating the patented drugs or medical apparatus and instruments, aiming at marketing these imitating products immediately after the expiration of the term of patent protection, would often need to produce, use or import such drugs or medical apparatus and instruments within the term of protection so as to conduct research and analysis to acquire, before hand, such data and other information necessary for the examination and approval. These acts are, of course, subject to authorization by the patent right holder and to payment of royalties, and would otherwise be considered acts of patent infringement. Nevertheless, if imitation and other related actions only commence after the expiration of the term of patent protection, no imitating products would be ready for circulation to the market immediately after the term of patent protection expires. In other words, during the period between the expiration of the term of protection and the time when imitating drugs or imitating medical apparatus and instruments are made available in the marketplace, nothing would be available as an alternative to the patented drugs or apparatus and

instrument, which would amount to a *de facto* extension of the term of patent protection. Such exception is thus provided for in the Patent Law to enable the public at large to obtain drugs or medical apparatus and instruments at a cheaper price after the expiration of the term of patent protection.

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

Such exceptions had not been provided for in the Patent Law of China that entered into force on April 1, 1985. It was later added to the Patent Law that entered into force on October 1, 2009.

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

Any person who produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, and any third party who produces or imports patented drugs or patented medical apparatus and instruments especially for that person.

55. The exception covers the regulatory approval of:

- any products
- certain products. Please describe which products: .....

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:

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):

No.

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

Yes.

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

No.

**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):

Article 69 of the Patent Law provides that the following shall not be deemed to be patent right infringement

(1) after a patented product or a product directly obtained by using the patented method is sold by the patentee or sold by any unit or individual with the permission of the patentee, any other person uses, offers to sell, sells or imports that product.

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

No.

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

Patent right holder enjoys exclusive right over his patent. However, such patent right would be exhausted once the patented products are lawfully sold out (which includes the selling by both the patent right holder and any one authorized by him), which means that the use, offering to sell, selling or other acts in relation to the sold-out products would be at the disposal of the buyer with no more authorization by the patent right holder. This is seen as a reasonable limitation on patents, serving the purpose of maintaining the normal economic order by avoiding restrictions on the circulation and use of the patented products in the marketplace.



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

Domestic exhaustion of patent had already been provided for in the Patent Law of China that entered into force on April 1, 1985, and such exception was later been modified in the Patent Law that entered into force on October 1, 2009 for this exception to also cover international exhaustion of patent.

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):

According to Article 69 of the Patent Law, after a patented product or a product directly obtained by using the patented method is sold by the patentee or sold by any unit or individual with the permission of the patentee, any one who uses, offers to sell, sells or imports that product shall not be deemed to be patent right infringement. The application of such exception does not take into consideration whether the patent right holder has any express notice on the product nor the content of such notice.

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

Yes.

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

No.

#### ***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):

Chapter VI of the Patent Law on "Compulsory License for Exploitation of a Patent" provides that, under any of the following circumstances, the patent administration department under the State Council may, upon application made by any unit or individual that possesses the conditions for exploitation, grant a compulsory license for exploitation of an invention patent or utility model patent:

- (1) where it has been three years since the date the patent right is granted and four years since the date the patent application is submitted, the patentee, without legitimate reasons, fails to have the patent exploited or fully exploited (Article 48 of the Patent Law);
- (2) where the patentee's exercise of the patent right is confirmed in accordance with law as monopoly and its negative impact on competition needs to be eliminated or reduced (Article 48 of the Patent Law);
- (3) where a national emergency or any extraordinary state of affairs occurs, or public interests so require (Article 49 of the Patent Law);
- (4) for the benefit of public health, the patent administration department under the State Council may grant a compulsory license for manufacture of the drug, for which a patent right has been obtained, and for its export to the countries or regions that conform to the provisions of the relevant international treaties to which the People's Republic of China has acceded (Article 50 of the Patent Law);
- (5) if an invention or utility model, for which the patent right has been obtained, represents a major technological advancement of remarkable economic significance, compared with an earlier invention or utility model for which the patent right has already been obtained, and exploitation of the former relies on exploitation of the latter, the patent administration department under the State Council may, upon application made by the latter, grant it a compulsory license to exploit the earlier invention or utility model (Article 51 of the Patent Law);

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

No.

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:

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

Such public policy objectives are: to prevent right holders from abusing their rights, to promote application of inventions and creations, to guarantee the normal operation of the patent system, and to safeguard the interests of the State and the public.

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

In the Patent Law as first promulgated in 1985, compulsory licenses had already been provided for, and its provisions have undergone various revisions and improvements over the years later on.

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

Under Rule 73 of the Implementing Regulations of the Patent Law of China, "insufficient exploitation of its or his patent" means the manner or scale of the exploitation of patent by the patentee and/or the licensee authorized by it or him cannot satisfy the demands of the domestic market for the patented product or patented process.

70. Does the importation of a patented product or a product manufactured by a patented process constitute "working" of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

According to the Patent Law, acts of importing the patented products or using the patented method to produce any products constitute "working" of the patent.

Specifically, Article 11 the Patent Law provides that "working of the patent" includes import the patented products, use the patented method, or

use, offer to sell, sell or import the products that are developed directly through the use of the patented method.

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?

Under Article 48 of the Patent Law, only when it has been three years since the date the patent right is granted and four years since the date the patent application is submitted can a compulsory license be granted on the grounds of non-working or insufficient working.

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"?

Where the patent right holder can prove that there exist justified reasons for his non-working, compulsory license of the patent shall be refused. For example, if the production, importing or marketing is prohibited by the Government, no compulsory license should be issued on the grounds of non-working or insufficient working.

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):

According to China's Patent Law, it does not constitute the grounds for any request for issuing compulsory licenses if "a patent right holder is requested to license the use of his patent, but fails to grant such license within a reasonably long period of time". Rather, non-working or insufficient working of the patented invention should constitute such grounds. Alternatively, compulsory licenses can also be requested on the grounds of dependent patents as procedural conditions.

Whether the conditions are reasonable or not should be determined by the specific circumstances of the invention or utility models concerned, such as their fields of technologies, marketing prospects, royalties of similar technologies, the funds invested in making the invention or utility models and so on. The criteria on what would constitute a reasonably long period of time should be determined by taking into consideration the time needed by the patent right holder to make a decision after having looking at both the economic and technological aspects of the inventions or utility models.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

The Patent Law allows for the grant of a compulsory license on the ground of elimination or reduction of the negative impact on competition. Upon entering into force of the administrative decision by any anti-monopoly agency or the judicial judgment by any court confirming that the patentee's exercise of his patent right constitutes monopoly, the patent administration department under the State Council may, upon application made by any unit or individual that possesses the conditions for exploitation, grant a compulsory license for exploitation of an invention patent or utility model in order to eliminate or reduce the negative impact of monopoly on competition.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

The grant of compulsory licenses on the ground of dependent patents must satisfy two conditions: first, there must be two inventions or utility models, the implementation of the latter invention or utility model being dependent on the implementation of the former; and second, the latter represents a major technological progress with greater economic significance as compared with the former.

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:

Article 57 of the Patent Law provides that the unit or individual that is granted a compulsory license for exploitation shall pay reasonable royalties to the patentee, or handle the issue of royalties in accordance with

the provisions of the relevant international treaties to which the People's Republic of China has acceded. The amount of royalties to be paid shall be subject to consultation between the two parties. In the event of failure to reach an agreement between the two parties, the patent administration department under the State Council shall make a ruling.

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:

No definition is given in China's Patent Law or Regulations to "national emergency" or "circumstances of extreme urgency". It is generally understood that wars or any emergency that endangers the country or any natural disasters or pandemic diseases would constitute cases of "national emergency" or "circumstances of extreme urgency".

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

No compulsory licenses have ever been issued in China.

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

Yes.

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

No.

#### *Government use*

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

Article 14 of the Patent Law provides that if an invention patent of a State-owned enterprise or institution is of great significance to national or public interests, upon approval by the State Council, the relevant competent departments under the State Council or the people's government of the provinces, autonomous regions, or municipalities directly under the Central

Government may decide to have the patent widely applied within an approved scope and allow the designated units to exploit the patent, and the said units shall pay royalties to the patentee in accordance with the regulations of the State.

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

No.

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

- 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: .....

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

Need may arise for invention patents to be widely applied and exploited in order to safeguard the national and public interest, and it is evident that this process would be excessively long if patent right holders have to license their patents to each and every licensee. In some instances, patent right holders may even place restrictions on the utilization of their patents or do not want their patents to be utilized on a large scale in the attempt to guarantee monopolized interests. In such cases, it is necessary for the State to exercise its administrative power and issue compulsory licenses to the patents concerned that may be owned by right-holders to allow them to be widely applied and exploited by designated entities.

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

Such exceptions had already been expressly provided for in the Patent Law of China that entered into force on April 1, 1985. Up to now, the Patent Law has been revised for three times, and the extent and procedures related to the compulsory use of some patents by the Government related to the exception have been the subjects for adjustment.

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:

No.

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

No.

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

Yes.

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

No.

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

*Farmers’ use of patented inventions*

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

No.

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

No.

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:

.....  
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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):]

No.

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

No.

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:

.....  
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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):

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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:

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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:

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.....

**Section XI: Other Exceptions and Limitations**

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

No.

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:

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

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.....  
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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?)

.....  
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.....

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

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.....  
.....

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:

Article 10 of the Regulations of China on the Protection of New Varieties of Plants provides that the exploitation of the protected variety may not require authorization from, or payment of royalties to, the variety rights holder for breeding and other scientific research activities, or for propagating purposes by farmers on their own holdings, without prejudice to other rights of the variety rights holder.

End of Questionnaire