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Section 1: General

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.

Under section 93 of the Patents Ordinance (Chapter 514, Laws of Hong Kong) (“PO”), ([http://www.legislation.gov.hk/blis_pdf.nsf/CurAllEngDoc/61E6148388730EF1482575EF0012A52E/\\$FILE/CAP_514_e_b5.pdf](http://www.legislation.gov.hk/blis_pdf.nsf/CurAllEngDoc/61E6148388730EF1482575EF0012A52E/$FILE/CAP_514_e_b5.pdf)) an invention is patentable if it is susceptible of industrial application, is new and involves an inventive step. An invention shall be considered (a) to be new if it does not form part of the state of the art (section 94 of PO), (b) as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art (section 96 of PO), and (c) as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture (section 97 of PO).

The above standard of patentability applies to all inventions irrespective of the technology involved.

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.

The following are not regarded as inventions and thus are not patentable:

- (a) a discovery, scientific theory or mathematical method;*
- (b) an aesthetic creation;*
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;*
- (d) the presentation of information (section 93(2) of PO).*

A method for treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body are not regarded as inventions susceptible of industrial application. However, a product, and in particular a substance or composition, for use in

the above method is patentable if it meets the standard for patentability set out in Question 1 above (section 93(4) of PO).

An invention the publication or working of which would be contrary to public order or morality shall not be a patentable invention (section 93(5) of PO).

A plant or animal variety or an essentially biological process for the production of plants or animals (other than a microbiological process or the products of such a process) are not patentable (section 93(6) of PO).

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?

A. Exclusive rights granted to a patent

The proprietor of a patent has the right to prevent all third parties not having his consent from doing the following acts in Hong Kong China:

(a) (in relation to any product that is the subject matter of the patent) making, putting on the market, using or importing the product or stocking the product whether for putting it on the market (in Hong Kong China or elsewhere) or otherwise;

(b) (in relation to a process which is the subject matter of the patent) using the process or offering the process for use in Hong Kong China when the third party knows or, or it is obvious to a reasonable person in the circumstances, that the use of the process without the consent of the proprietor of the patent is prohibited;

(c) (in relation to any product obtained by means of any patented process) putting on the market, using or importing the product or stocking the product, whether for the purpose of putting it on the market (in Hong Kong China or elsewhere) or otherwise.

(Section 73 of PO)

Furthermore, the proprietor also has the right to prevent all third parties not having his consent from supplying or offering to supply in Hong Kong China a person with the means (relating to an essential element of the patented invention) for putting the invention into effect when the third party knows, or it is obvious in the circumstances to a reasonable person, that the said means are suitable and intended for putting that invention into effect in Hong Kong China (section 74 of PO).

B. Exclusive rights granted by publication of a patent application

There are 2 types of patents in Hong Kong China – (i) standard patent with a term of 20 years and (ii) short-term patent with a term of 8 years. The following provisions regarding exclusive rights accorded by publication of a patent application applies only to standard patents.

Where an application for a standard patent is published, the applicant shall have, as from the date of publication and until the grant of the standard patent, the same right as he would have had, if the patent had been granted on the date of the publication of the application, to bring proceedings in the court for damages in respect of any act which would have infringed the patent. However, the applicant shall only be entitled to bring proceedings in respect of any act only-

(a) after the standard patent is granted; and

(b) (assuming that the patent had been granted on the date of publication of the request to record) if the act would have infringed not only the standard patent, but also the claims in the form in which they were contained in the published request to record.

(section 88 of PO)

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;

Compulsory licensing and/or government use.

Section 2: Private and/or non-commercial use

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

Section 75(a), PO.

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

N/A

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

It was considered that acts that are both private (i.e. not carried out in public and merely for the person's own use and benefit) and non-commercial should be exempted from infringement.

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

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular, section 42 of the Irish Patents Act 1992.

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):

Not defined in the PO.

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):

N/A.

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, it has been working well so far.

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

We have not encountered any challenge so far.

Section 3: Experimental use and/or scientific research

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

Section 75(b), PO.

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

N/A.

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

It was considered that acts done for experimental purposes should be exempted if they relate to the subject-matter of an invention. This would include, for example, trials carried out in order to discover something unknown, or to test a hypothesis, or even in order to find out whether something which is known to work in specific conditions would work in different conditions.

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

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular, section 42 of the Irish Patents Act 1992.

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

No.

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):

Not defined.

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:

The purpose of the experiment is not specifically set out in section 75(b) of the PO. The court will determine whether a particular act comes within the scope of the exception based on the facts and circumstances of each case.

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”).

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

Section 75(b) of PO provides that the rights conferred by a patent shall not extend to acts done for experimental purposes relating to the subject matter of the relevant patented invention.

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:

The commercial intention of the experimentation and/or research is not relevant.

19.-20.

N/A

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, it has been working well so far.

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

We have not encountered any challenge so far.

Section 4: Preparation of medicines

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

Section 75(c), PO.

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

N/A

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

It was considered that extemporaneous preparation of a medicine for individual cases in a pharmacy in accordance with specific medical prescriptions should be exempted from infringement.

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

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular, section 42 of the Irish Patents Act 1992.

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

Pharmacists working in a pharmacy who prepare medicine as and when required based on specific prescriptions.

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

No.

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):

Section 75(c) of PO requires that the preparation of a medicine must be in accordance with a medical prescription issued by a registered medical practitioner or registered dentist.

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:

Yes, it has been working well so far.

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

We have not encountered any challenge so far.

Section 5: Prior use

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

Section 83, PO.

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

N/A

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

It was considered that, where there has been a prior secret use of the claimed invention by a third party, the exception should provide such party with a right to continue his prior acts unaffected by the grant of the patent. However, the right provided would serve as a personal defense to an allegation of infringement and cannot be licensed to others.

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

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular, section 55 of the Irish Patents Act 1992.

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):

Pursuant to section 83 of PO, where a patent is granted for an invention, any person in Hong Kong China who, before the deemed date of filing of the application for the standard patent or the date of filing of the application for the short-term patent or, if priority was claimed, before the date of priority –

(a) does in good faith an act which would constitute an infringement of the patent if it were in force, or

(b) makes in good faith effective and serious preparations to do such an act shall have the right to continue to do the act above.

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

No.

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

Yes (The right can be assigned but it cannot be licensed to others).

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.

If yes, please explain what those conditions are:

If the prior act (which would constitute an infringement of the patent if it were in force) was done or preparations had been made to do it in the course of a business, the prior right user shall have the following rights -

(a) where the prior right user is an individual:

(i) he could assign the right to do the act in question or transmit such right on death, or

(ii) he could authorize the doing of that act by any of his partners for the time being in the business in the course of which the act was done or preparations had been made to do it.

(b) in the case of a body corporate, it would be entitled to assign the right to do the act or to transmit such right on the body's dissolution.

However, the prior right user does not have the right to grant a licence to any person to do the act in question (section 83(2) & (3) of PO).

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?

No.

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):

N/A

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, it has been working well so far.

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

We have not encountered any challenge so far.

Section 6: 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):

Section 75(d), (e) and (f) of PO.

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

N/A

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

It was considered that foreign vessels, aircraft, land vehicles and aircraft coming temporarily into Hong Kong should be exempted from claims of patent infringement.

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

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular section 42 of the Irish Patents Act 1992.

45. The exception applies in relation to:

*Vessels;
Aircrafts;
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):

Exceptions involving vessels, aircraft and land vehicles are set out in three provisions under the PO. They are sections 75(d), (e) and (f).

Sections 75(d) and 75(e)

It is expressly stipulated in section 75(d) (which applies to vessels) and section 75(e) (which applies to aircraft, hovercraft and land vehicles) that the exceptions would apply if the above transportation vehicles have "temporarily or accidentally" entered Hong Kong China.

The expression "temporarily or accidentally" is not defined in the PO. It should be construed based on its ordinary and natural meaning.

Section 75(f)

This provision applies to aircraft that has lawfully entered or is lawfully crossing Hong Kong. This provision is in line with the obligations under article 27 of the Chicago Convention of which China is a member.

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):

Section 75(d) of PO provides that the right of a patent shall not extend to the use of the invention which is the subject of the patent-

(i) on board vessels registered in any of the Paris Convention countries or WTO member countries, territories or areas, other than Hong Kong China; or

(ii) in the body of such vessels, or in the machinery, tackle, gear or other accessories of such vessels, when such vessels temporarily or accidentally enter the territorial waters of Hong Kong China, but only if the invention is used in such waters exclusively for the needs of the vessel.

Section 75(e) of PO provides that the right of a patent shall not extend to the use of the invention which is the subject of the patent in the construction or operation of-

(i) aircraft, hovercraft or land vehicles of Paris Convention countries or WTO member countries, territories or areas, other than Hong Kong China; or

(ii) such aircraft, hovercraft or land vehicle accessories,

when such aircraft, hovercraft or land vehicles temporarily or accidentally enter Hong Kong China.

Section 75(f) of PO provides that the right of a patent shall not extend to the use of an aircraft which has lawfully entered or is lawfully crossing Hong Kong China, or the importation into Hong Kong China or the storage thereof, of any part or accessory of such aircraft. This provision only applies where the Central People's Government of China has made a declaration with a view to the fulfillment of the provisions in the Chicago Convention.

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):

Please see answer to Q.47.

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, it has been working well so far.

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

We have not encountered any challenge so far.

Section 7: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: The applicable law of Hong Kong China does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section 8: Exhaustion of patent rights

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

Exhaustion doctrine is not expressly addressed in PO and there is yet no Hong Kong case on this subject. The position on exhaustion doctrine is unclear in Hong Kong China.

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

N/A

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

N/A

61.-64.

N/A

Section 9: Compulsory licensing and/or government use

Compulsory licenses

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

*Compulsory licences for standard patents (sections 64-67 of PO);
Import compulsory licences for patented pharmaceutical products (sections 72A-72J of PO);
Export compulsory licences for patented pharmaceutical products (sections 72K-72R of PO).*

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

N/A

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;
Public health;
National emergency and/or extreme urgency;
Dependent patents.*

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

Compulsory licences on grounds of non-working or insufficient working of patent etc.
The objective underlying the grant of compulsory licences is to prevent abuse of monopoly rights by patent proprietors and to encourage manufacture. They ensure that patented inventions are applied practically to their fullest extent and patent rights are exercised without prejudice to the development of industry.

Import and export compulsory licences for patented pharmaceuticals
The objective of the provisions on import compulsory licences is to enable Hong Kong China to make use of the system under the Protocol amending the TRIPs Agreement (adopted by the General Council of the WTO on 6 December 2005) to import medicine in situations of national emergency or other circumstances of extreme urgency.
Regarding export compulsory licences, the objective is to allow manufacturers in Hong Kong China to make use of the Protocol to make and export pharmaceutical products to other WTO members who declare that it is under national emergency or other circumstances of extreme urgency.

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

Compulsory licences on grounds of non-working or insufficient working of patent etc.
In formulating the provisions on compulsory licences, we have made reference to the laws of other jurisdictions and in particular sections 48-50 and section 52 of the United Kingdom Patents Act 1977.

Import and export compulsory licences for patented pharmaceuticals
Please refer to Question 68(a) above.

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

The concepts of “non-working” and “insufficient working” are reflected in section 64(2) of PO which sets out the grounds upon which a person may apply for the grant of compulsory licence from the court.

These grounds are:

- (a) where the patented invention is capable of being commercially worked in Hong Kong China, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable (section 64(2)(a) of PO);*
- (b) where the patented invention is a product, that a demand for the product in Hong Kong China is not being met on reasonable terms (section 64(2)(b));*
- (c) where the patented invention is capable of being commercially worked in Hong Kong by manufacture, that it is being prevented or hindered from being so worked-*
 - (i) in the case of a product, by the importation of the product; or*
 - (ii) in the case of a process, by the importation of a product obtained directly by means of the process or to which the process has been applied (section 64(2)(c));*
- (d) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms-*
 - (i) the working or efficient working in Hong Kong China of any other patented invention which involves an important technical advance of considerable economic significance in relation to the patent is prevented or hindered; or*
 - (ii) the establishment or development of commercial or industrial activities in Hong Kong China is unfairly prejudiced (section 64(2)(d)); and*
- (e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent or the establishment or development of commercial or industrial activities in Hong Kong China, is unfairly prejudiced (section 64(2)(e)).*

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):

Yes.

According to section 6(4) of PO, unless the context otherwise requires, a reference in PO to an invention being worked in Hong Kong includes a reference to the invention being worked by importation into Hong Kong for the purpose of putting the patented on the market or stocking it for that purpose.

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

If yes, what is the time period?

After the expiration of 3 years from the date of grant of a standard patent (section 64(1) of PO).

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.

If yes, what are “legitimate reasons”?

The patentee may provide reasons to support his argument that the time elapsed since the grant of the patent has been insufficient to enable the invention to be commercially worked (or worked to its fullest extent). The court may, if it satisfied with the reason(s) given by the patentee, adjourn the hearing to allow sufficient time for the patentee to exploit the patent (section 64(4) of PO). The PO does not contain an exhaustive list of legitimate reasons. However, the court will consider whether justifiable reasons are given by the patentee based on the facts and circumstances of each case.

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):

Compulsory licences on grounds of non-working or insufficient working of patent etc. Where an applicant applies for the grant of a compulsory licence from the court based on any of the grounds set out in Question 69, he has to satisfy the court that he has made reasonable efforts to obtain authorization from the proprietor on “reasonable commercial terms and conditions” and that such efforts have not been successful within “a reasonable period of time” (section 64(5) of PO).

The PO does not provide a definition for the above expressions. The court will decide whether the above condition is satisfied based on the facts and circumstances of each case.

Export compulsory licences for patented pharmaceuticals

Before an applicant makes an application to the Director of Health of Hong Kong China for an export compulsory licence, it should make reasonable efforts to obtain authorization from the proprietor of the patent concerned on reasonable commercial terms and conditions. The Director of Health will only consider granting the licence if the applicant has failed to obtain authorization within 28 days. The above requirement would not apply if, at the time of application of the export licence by the applicant, the importing member has declared that it was under national emergency or other circumstances of extreme urgency (section 72L(4) of PO).

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):

None.

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:

One of the grounds for application of a compulsory licence is that the proprietor of the patent has refused to grant a licence on reasonable terms and as a result, the working or efficient working of any other patented invention is prevented or hindered. However, the dependent patent must involve an important technical advance of considerable economic significance in relation to the patent that is the subject matter of the compulsory licence (section 64(2)(d) of PO).

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:

*Compulsory licences on grounds of non-working or insufficient working of patent etc.
When exercising its power to grant compulsory licences, the court is required to ensure that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention (section 66(1)(b) of PO).*

Import compulsory licences for patented pharmaceuticals

(a) No remuneration is payable to the proprietor of the patented pharmaceutical product in Hong Kong China for such a licence if remuneration has been paid to the proprietor of the patent in the exporting country for production and export of the product to Hong Kong China.

(b) Where remuneration mentioned in paragraph (a) above has not been paid and all legal remedies to recover the payment in the exporting country have been exhausted, the Government of the Hong Kong Special Administrative Region, China (HKSAR Government) shall pay such amount of remuneration:

(i) as may be agreed by the Director of Health, HKSAR Government and the proprietor of the patent in Hong Kong China. The total amount of remuneration agreed shall not exceed 4% of the total purchase price for the product payable by the import compulsory licensee to the seller of the product in the exporting member; or

(ii) if the remuneration cannot be agreed under paragraph (i) above, either party may apply to court for determination of the amount payable. In determining the amount, the court will take into account all factors relevant to the circumstances, including

- the economic value to Hong Kong China of the use of the relevant patented pharmaceutical product;

- humanitarian or non-commercial factors relevant to the grant of the licence.

The amount determined by the court would not be subject to the maximum limit under paragraph (i) above.

(sections 72E and 72J of PO)

Export compulsory licences for patented pharmaceuticals

(a) The amount of remuneration to be paid by the export compulsory licensee to the proprietor of the patent shall be determined by the Director of Health of HKSAR Government. Such amount shall not exceed 4% of the total purchase price for the product payable by the importing member to the export compulsory licensee.

(b) Any party aggrieved by the determination made by the Director of Health, HKSAR Government may apply to court for a review. In determining the appropriate amount of remuneration, the court will take into account all factors relevant to the circumstances including

- the economic value to the eligible importing member of the use of the relevant patented pharmaceutical product exported to it;

- humanitarian or non-commercial factors relevant to the grant of the licence.

(sections 72P and 72R of PO)

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:

In relation to import compulsory licences, the Chief Executive in Council of the HKSAR Government may declare a period of extreme urgency if it is necessary or expedient in the public interest to do so to address any public health problem or threatened public health problem in Hong Kong China. During such period, if the Director of Health of HKSAR Government considers that Hong Kong China has no or insufficient capacity to manufacture a patented pharmaceutical product to meet the needs for the product in Hong Kong China, the Director of Health may grant an import compulsory licence to a public officer or any other person to import, put on the market, stock or use the product in Hong Kong China (sections 72B and 72C of PO).

In relation to export compulsory licences, these may be granted on the basis that the importing member has notified TRIPs Council that it is faced with a national emergency or other circumstances of extreme urgency. If the importing member has not so notified the TRIPs Council, the proposed compulsory licensee must make reasonable efforts to obtain authorization from the proprietor of the patent concerned prior to submitting his application for an export compulsory licence (section 72L of PO). “National emergency” or “circumstances of extreme urgency” are not defined in the PO and should be construed based on their ordinary meanings. Examples of such circumstances may include public health problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

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

None.

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, it has been working well so far.

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

We have not encountered any challenge so far.

Government use

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

Sections 68-72, PO.

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

N/A

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

Extreme urgency (section 69, PO).

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

The relevant sections confer powers on the HKSAR Government during a period of extreme urgency (declared by the Chief Executive in Council of HKSAR Government) to use patented inventions or an invention which is the subject of a published pending application, without the consent of the patent proprietor. The purpose was to allow immediate use of these inventions to meet the urgent needs of the community during a period of extreme urgency.

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

In formulating the relevant provisions, we have made reference to the laws of other jurisdictions and in particular sections 55-59 of the United Kingdom Patents Act 1977.

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:

A period of extreme urgency may be declared where it is necessary or expedient in the public interest for the maintenance of supplies and services essential to the life of the community or for securing sufficient supplies and services essential to the life of the community (section 68 of PO). Examples of such extreme urgency may include massive health crisis.

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

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:

Yes, it has been working well so far.

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

We have not encountered any challenge so far.

Section 10: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

89.-100.

There are no exceptions and limitations related to farmers' and/or breeders' use of patented inventions.

Section 11: Other exceptions and limitations

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

Second or further medical uses of a known substance or composition.

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

The court in Hong Kong China affirmed in Abbott GMBH & Anor v Pharmareg Consulting Company Ltd & Anor [2009] 3 HKLRD 524 that second medical uses may be protected by patents using Swiss-type claims. This case relates to a standard patent granted in Hong Kong China for the use of a known chemical compound, Sibutramine, in the manufacture of medicaments for the treatment of obesity. Previously it was not known that the above compound could be used to treat obesity. In this case, the Court considered that there was novelty, not in the method of such use but in the new therapeutic purpose for which the substance was used and such second medical use could be protected by Swiss-type claims.

(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:

See Q102(i) above.

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

In the above case, the Court held that second medical use in Swiss-type claims must be for an end-purpose distinctively different from the first even though it was also for medical purposes.

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?):

We believe that the courts in Hong Kong China will continue to acknowledge the validity of patents for second or further medical uses using Swiss-type claims. Currently, the HKSAR Government is conducting a review of the local patent system which involves consideration of whether any legislative amendment on this issue should be introduced.

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

We have not encountered any practical problems so far.

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:

N/A

[End of Questionnaire]