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LEGISLATIVE COUNCIL BRIEF

Patents Ordinance
(Chapter 514)

PATENTS (AMENDMENT) BILL 2007

INTRODUCTION

At the meeting of the Executive Council on 20 March 2007, the Council ADVISED and the Chief Executive ORDERED that the Patents (Amendment) Bill 2007 ("the Bill"), at Annex A, should be introduced into the Legislative Council.

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JUSTIFICATIONS

The Protocol

2. The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") of the World Trade Organisation ("WTO") contains provisions governing the protection of patent. The proprietor of a patent has various exclusive rights including the right to make, use, sell or import the patented product or the product obtained directly by the patented process. Any other person who wants to do an act restricted by patent requires prior authorisation from the proprietor of the patent, or else he renders himself liable to civil action.

3. In November 2001, the Ministerial Conference of the WTO in Doha recognised the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics. More specifically, it was noted that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of the existing compulsory licensing system[1] under the TRIPS Agreement, in that they could not appeal to other economies with manufacturing capacity to export generic medicines (i.e. generic versions of patented pharmaceutical products) to them. This is because by virtue of Article 31(f) of the TRIPS Agreement, the majority of the product made under a compulsory licence should be predominantly for the supply of the domestic market, not being for export.

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[1] A compulsory licence allows a third party to use a patent invention without the authorisation of the right holder.

4. In August 2003, the General Council of the WTO decided to temporarily waive the obligations set out in Article 31(f) and Article 31(h)[2] of the TRIPS Agreement in specified circumstances. In effect, the decision allows pharmaceutical products made under compulsory licences in one WTO Member to be exported, *without* the restriction of Article 31(f), to another WTO Member lacking production capacity. It also avoids double remuneration. Where adequate remuneration is paid pursuant to Article 31(h) in the WTO Member which exports a pharmaceutical product, no remuneration is required to be paid in the WTO Member which imports the product.

5. On 6 December 2005, the General Council of the WTO further adopted the Protocol which would, subject to paragraph 6 below, replace the temporary waiver and give permanent effect to the arrangements.

6. The Protocol is open for acceptance by WTO Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference of the WTO. The Protocol will take effect upon acceptance by two thirds of the WTO Members.

7. The Protocol facilitates access to generic medicines for addressing public health problems. The existing Patents Ordinance (Cap. 514) ("the Ordinance") would have to be amended before Hong Kong could make use of the Protocol. We intend to notify the WTO of Hong Kong's acceptance of the Protocol after the passage and enactment of the Bill.

Hong Kong to import pharmaceutical products under the Protocol

8. As the Protocol is meant for helping developing and least-developed economies to gain access to medicines, some WTO Members (mainly the developed economies) have indicated that they would not use the system under the Protocol to import medicine. Some other WTO Members including Hong Kong have declared that they would not use the system as an importer unless in situations of national emergency or other circumstances of extreme urgency.

9. We propose that the Chief Executive-in-Council may declare a period of extreme urgency in Hong Kong by way of notice in the Gazette if it is considered necessary or expedient in the public interest to do so to address any public health problem[3]. During such a period of extreme urgency, if the Director of Health ("the DH") considers that Hong Kong has insufficient or no manufacturing capacity to make a certain pharmaceutical product to contain the public health problem in question, Hong Kong may use the Protocol to import the product. The DH may grant a

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[2] According to Article 31(h) of the TRIPS Agreement, where a patent is used under a compulsory licence, the proprietor of the patent has to be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the use under authorisation.

[3] This formulation is in line with the existing section 68 of the Ordinance which relates to the use by the government of patented inventions in general in circumstances of extreme urgency.

compulsory licence to any person to import, use, put on market, or stock the pharmaceutical product, or do any other act which would otherwise amount to an infringement of the patent concerned, without the consent of the proprietor of the patent ("import compulsory licence"). The DH should, as soon as practicable, notify the proprietor of the patent the grant of the import compulsory licence.

10. In line with the requirements in the Protocol, the import compulsory licence would be subject to the following conditions -

(a) the entire quantity of the pharmaceutical product imported under the licence should be for use in Hong Kong only, and not for export to other places; and

(b) the pharmaceutical product should be clearly identified, through specific labelling or marking, as being produced pursuant to the Protocol.

11. The issue of paying adequate remuneration to the proprietor of the patent is being addressed in paragraphs 15-18 below.

Hong Kong to export pharmaceutical products under the Protocol

12. If a WTO Member indicates that it intends to avail itself of the Protocol to source a certain pharmaceutical product, any local manufacturer may, subject to the issue of a compulsory licence by the DH, make use of the Protocol to make and export the product to the concerned Importing Member ("export compulsory licence").

13. We propose that an applicant, before applying for an export compulsory licence, should make reasonable efforts to obtain an authorisation from the proprietor of the patent on reasonable commercial terms and conditions. The DH would only consider granting the licence if the applicant has failed to obtain the authorisation within 28 days. For cases where the Importing Member has declared that it is under national emergency or other circumstances of extreme urgency, the foregoing requirement would not apply. Upon granting of an export compulsory licence, the DH should, as soon as practicable, notify the proprietor of the patent the grant of the licence.

14. We propose that, when granting an export compulsory licence, the DH may impose terms and conditions he considers appropriate, including but not limited to the following as required under the Protocol –

(a) only the amount necessary for meeting the public health needs of the Importing Member may be produced and the entirety of this production shall be exported to that Importing Member;

(b) the pharmaceutical product should be clearly identified, through specific labelling or marking, as being produced pursuant to the Protocol; and

(c) before shipment, the licensee shall post on a designated website specific information about the product supplied to the Importing Member.

Remuneration to the proprietor of the patent

15. Under the Protocol, where a compulsory licence is granted by an Exporting Member, adequate remuneration shall be paid to the proprietor of the patent in that Member. The amount of remuneration payable should be determined taking into account the economic value of the use of the pharmaceutical product to the Importing Member. If adequate remuneration is paid at the exporting end, no remuneration is required to be paid at the importing end.

16. In line with the requirements under the Protocol, the holder of an export compulsory licence granted in Hong Kong should pay remuneration to the local proprietor of the patent. We propose that the amount of remuneration should be determined on a case-by-case basis by the DH on the advice of the Director of Intellectual Property ("the DIP"). This amount, however, would not exceed a level equivalent to 4% of the total price to be paid by the importer for the product. In drawing up this 4% cap, we have taken into account the mechanisms adopted by the European Union, Canada and Switzerland. They have prescribed (or are about to prescribe) a maximum rate or a formula for calculating the amount of remuneration (and, in both cases, the amount generally does not exceed a level equivalent to 4% of the total price to be paid by the importer for the product). Where a pharmaceutical product involves more than one patent, the amount of remuneration should be divided equally among the proprietors of the concerned patents (also for the import scenario in paragraph 17 below).

17. Where Hong Kong imports a pharmaceutical product under the Protocol, an obligation to pay remuneration to the proprietor of the patent in Hong Kong will only arise if adequate remuneration is not paid in accordance with the Protocol after all legal remedies to recover the payment of the remuneration at the exporting end have been exhausted. Under such extremely rare circumstances, we propose that the Government, instead of the holder of the import compulsory licence, should pay the remuneration to the proprietor of the patent in Hong Kong since the pharmaceutical product is used to contain an urgent public health problem in Hong Kong. The amount of remuneration would be agreed between the proprietor of the patent and the DH on the advice of the DIP. Similarly, we propose a cap equivalent to 4% of the total price paid by the Hong Kong importer for the product.

18. The propriety of the cap may be reviewed in the course of time, having regard to the prevailing international practice. We thus propose that the Secretary for Commerce, Industry and Technology may, by way of notice in the Gazette, vary the said percentage in paragraphs 16 and 17 above.

Appeal Mechanism

19. Any party aggrieved by the decision of the DH in relation to the grant of a compulsory licence to import or export a pharmaceutical product under the Protocol may apply to the court for review. The court may by order vary or cancel the licence or make such other order as it thinks fit. Moreover, any dispute regarding the remuneration may be referred to the court. In determining the appropriate amount of remuneration, the court may order an amount higher than the cap (in paragraphs 16 and 17 above) if it is satisfied that the maximum level of payment does not constitute adequate remuneration for the use of the patented pharmaceutical product, taking into account (a) the humanitarian and non-commercial considerations underlying the authorisation of the compulsory licence; and (b) the economic value of the use of the product to the Importing Member. The proposed appeal mechanism is in line with the requirement under the TRIPS Agreement.

Safeguards against trade diversion

20. The Protocol requires WTO Members to take reasonable measures preventing re-exportation of the products imported into their territories under the system. It also requires the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted into their markets. In Hong Kong, legal provisions that meet the above requirements already exist. These include (i) the civil remedies available under the Ordinance against importation and sale of products which infringe patents; and (ii) the criminal sanctions available under the Import and Export Ordinance (Cap. 60) against the importation and exportation of pharmaceutical products without valid import and export licences.

THE BILL

21. The main provisions in the Bill are described below –

(a) Clause 3 defines, amongst other things, the meaning of "eligible importing member", "exporting member", "patented pharmaceutical product" and "pharmaceutical product";

(b) Clause 5 adds two new parts to the Ordinance –

(i) Part IXA governs the grant of import compulsory licences for patented pharmaceutical products. The proposed new section 72B empowers the Chief Executive-in-Council to declare a period of extreme urgency for the purposes of applying provisions relating to the import compulsory licences to address any public health problem or threatened public health problem in Hong Kong. The proposed new sections 72C and 72G empower the DH to grant and

terminate import compulsory licences. The proposed new section 72D provides that certain terms and conditions are to be imposed on such licences. The proposed new section 72E governs the payment of remuneration to the local proprietor of the patent concerned by the Government under special circumstances (please see paragraph 17 above). The proposed new section 72I provides that the court may handle various disputes in relation to import compulsory licences; and

(ii) Part IXB governs the grant of export compulsory licences for patented pharmaceutical products. The proposed new section 72K provides for applications for export compulsory licences and the requirements to be met. The proposed new sections 72L and 72P empower the DH to grant and terminate export compulsory licences under certain circumstances. The proposed new section 72M provides that certain terms and conditions are to be imposed on such licences. The proposed new section 72O governs the determination of the remuneration payable to the local proprietor of the patent concerned for the making and exportation of the patented pharmaceutical products under export compulsory licences (paragraph 16 above). The proposed new section 72Q provides that the court may handle various disputes in relation to export compulsory licences.

B 22. The existing provisions of the Ordinance being amended are at Annex B.

LEGISLATIVE TIMETABLE

23. The legislative timetable is as follows –

Publication in the Gazette	30 March 2007
First Reading and commencement of Second Reading debate	18 April 2007
Resumption of Second Reading debate, Committee Stage and Third Reading	to be notified

IMPLICATIONS OF THE PROPOSAL

24. The proposal has economic, financial and civil service and sustainability
C implications as set out at Annex C. It has no productivity and environmental implications. It does not affect the current binding effect of the Ordinance and in respect of the part relating to the import of a pharmaceutical product, the proposal applies to the Government. The proposal is in conformity with the Basic Law, including provisions concerning human rights.

PUBLIC CONSULTATION

25. We consulted the relevant stakeholders on the proposed amendments in late 2006, including the major medical, legal and intellectual property practitioners' associations, the major trade associations representing the pharmaceutical industry, local universities, as well as relevant non-governmental organisations (NGOs). The respondents in general gave in-principle support to the proposal. Nevertheless, manufacturers of patented pharmaceutical products and some intellectual property practitioners had argued for removal of the cap on the remuneration payable to the local proprietor of the patent.

26. We consulted the Panel on Commerce and Industry of the Legislative Council on 19 December 2006. Members present indicated in-principle support for the proposed amendments.

PUBLICITY

27. A press release will be issued on 30 March 2007. A spokesman will be made available to answer enquiries.

ENQUIRIES

28. Any enquiries on this brief may be addressed to Ms Priscilla TO, Principal Assistant Secretary of Commerce, Industry and Technology (Commerce and Industry) at telephone number 2918 7480.

Commerce and Industry Branch
Commerce, Industry and Technology Bureau
28 March 2007

Annex A

PATENTS (AMENDMENT) BILL 2007

CONTENTS

PART IXB

EXPORT COMPULSORY LICENCES FOR PATENTED PHARMACEUTICAL PRODUCTS

A BILL

To

Amend the Patents Ordinance to implement the Protocol Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organisation in relation to patents and public health; and to provide for incidental and related matters.

Enacted by the Legislative Council.

1. Short title

This Ordinance may be cited as the Patents (Amendment) Ordinance 2007.

2. Commencement

This Ordinance shall come into operation on a day to be appointed by the Secretary for Commerce, Industry and Technology by notice published in the Gazette.

3. Interpretation

Section 2(1) of the Patents Ordinance (Cap. 514) is amended by adding –

""eligible importing member" (合資格進口成員地) means –

(a) a WTO member country, territory or area recognized by the United Nations as being a least-developed country; or

(b) any other WTO member country, territory or area that has given notice in writing to the TRIPS Council that it intends to import pharmaceutical products in accordance with Article 31 bis in the Protocol;

"exporting member" (出口成員地) means a WTO member country, territory or area that makes a patented pharmaceutical product for export to an eligible importing member in accordance with Article 31 bis in the Protocol;

"patented pharmaceutical product" (專利藥劑製品) means –

(a) a pharmaceutical product which is an invention for which a standard patent or a short-term patent (as the case may be) has been granted;

(b) in relation to a process for which a standard patent or a short-term patent (as the case may be) has been granted, a pharmaceutical product obtained directly by means of the process or to which the process has been applied;

"pharmaceutical product" (藥劑製品) means –

(a) a pharmaceutical product within the meaning of section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138);

(b) an active ingredient that is needed for making of a pharmaceutical product mentioned in paragraph (a); or

(c) a diagnostic kit that is needed for the use of a pharmaceutical product mentioned in paragraph (a);

"Protocol" (《日內瓦議定書》) means the Protocol Amending the TRIPS Agreement adopted by the General Council of the WTO at Geneva on 6 December 2005;

"TRIPS Agreement" (《知識產權協議》) means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the World Trade Organisation Agreement;

"TRIPS Council" (知識產權理事會) means the Council for Trade-Related Aspects of Intellectual Property Rights referred to in Article 68 of the TRIPS Agreement;

"WTO" (世界貿易組織) means the World Trade Organisation established in Geneva on 1 January 1995 under the World Trade Organisation Agreement;".

4. Special provision regarding invention covered by 2 or more patents

Section 9 is amended by repealing "or the provisions of Part IX relating to Government use" and substituting ", the provisions of Part IX relating to Government use, an import compulsory licence having effect under Part IXA or an export compulsory licence having effect under Part IXB".

5. Parts IXA and IXB added

The following are added immediately before Part X –

"PART IXA

IMPORT COMPULSORY LICENCES FOR PATENTED PHARMACEUTICAL PRODUCTS

72A. Interpretation of Part IXA

In this Part, unless the context otherwise requires –

"Director" (署長) means the Director of Health;

"import compulsory licence" (進口強制性特許) means a compulsory licence granted under section 72C;

"import compulsory licensee" (進口強制性特許持有人) means the holder of an import compulsory licence;

"proprietor" (所有人), in relation to a patent, means the proprietor of the patent that is granted in Hong Kong.

72B. Declaration of extreme urgency for public health problem

(1) The Chief Executive in Council may, for the purposes of applying sections 72C to 72I, by notice published in the Gazette declare a period of extreme urgency whenever the Chief Executive in Council considers it to be necessary or expedient in the public interest to do so to address any public health problem or threatened public health problem in Hong Kong.

(2) A notice published under subsection (1) is subsidiary legislation.

72C. Grant of import compulsory licences for patented pharmaceutical products

During a period of extreme urgency declared under section 72B(1), where the Director considers that the pharmaceutical industry in Hong Kong has no or insufficient capacity to manufacture a patented pharmaceutical product to meet the needs for the product in Hong Kong, the Director may grant an import compulsory licence under the patent concerned, subject to such terms and conditions as he may impose, to a public officer or any other person to do in Hong Kong in relation to the product all or any of the following which appears to the Director to be necessary or expedient in connection with the extreme urgency giving rise to the declaration –

(a) importing, putting on the market, stocking or using the product;

(b) any other act which would, apart from this section, amount to an infringement of the patent concerned.

72D. Terms, conditions and nature of import compulsory licences

(1) The terms and conditions subject to which an import compulsory licence is granted under section 72C shall include –

(a) terms and conditions in respect of –

(i) the acts authorized to be done in relation to the patented pharmaceutical product under the licence;

(ii) the amount of the patented pharmaceutical product covered by the licence; and

(iii) the duration of the licence;

(b) terms and conditions providing that –

(i) the patented pharmaceutical product which is imported to Hong Kong under the licence shall not be exported out of Hong Kong;

(ii) the patented pharmaceutical product shall be –

(A) clearly identified as being imported under the licence through specific labelling or marking; and

(B) distinguished from the same product made by or under authorization of the proprietor of the patent concerned through special packaging, colouring or shaping; and

(iii) the licence is non-assignable except with that part of the enterprise or goodwill which enjoys the use of the patent under the licence; and

(c) any other terms or conditions as the Director thinks fit having regard to the public health needs in Hong Kong in the period of extreme urgency declared under section 72B(1).

(2) An import compulsory licence is non-exclusive.

72E. Payment of remuneration to proprietors of patents

(1) If remuneration has been paid to the proprietor of a patent granted in an exporting member for a patented pharmaceutical product to be exported to Hong Kong in accordance with Article 31 bis in the Protocol and Article 31(h) of the TRIPS Agreement, no remuneration shall be paid to the proprietor of the patent concerned granted in Hong Kong for the import compulsory licence in relation to the product.

(2) If the proprietor of the patent concerned granted in Hong Kong establishes to the satisfaction of the Government that remuneration has not been paid to the proprietor of the patent granted in the exporting member for the production and export of the patented pharmaceutical product to Hong Kong in accordance with Article 31 bis in the Protocol and Article 31(h) of the TRIPS Agreement and all legal remedies to recover payment of the remuneration in the exporting member have been exhausted, the Government shall pay to the proprietor of the patent concerned granted in Hong Kong such amount of remuneration –

(a) as may be agreed between the Director and the proprietor of the patent concerned granted in Hong Kong subject to any order made by the court on an application under section 72I(2); or

(b) as may be determined by the court on an application under section 72I(1) or (2),

for the import compulsory licence in relation to the product.

(3) Before reaching any agreement as to the amount of remuneration, the Director shall take into account any advice given by the Director of Intellectual Property as regards the remuneration.

(4) The total amount of remuneration agreed under subsection (2)(a) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) 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.

(5) Where there is more than one patent in relation to the patented pharmaceutical product, the total amount of remuneration agreed under subsection (2)(a) shall be apportioned on an equal share basis among all the proprietors of the patents concerned.

(6) The Secretary for Commerce, Industry and Technology may by notice published in the Gazette vary the percentage specified in subsection (4).

72F. Notification of grant of import compulsory licences and remuneration agreed, etc.

(1) The Director shall as soon as practicable after the grant of an import compulsory licence under section 72C –

(a) give notice in writing to the proprietor of the patent concerned of the grant of the licence and its terms and conditions; and

(b) advertise in the official journal notice of the grant of the licence and its terms and conditions.

(2) The Director shall advertise in the official journal –

(a) a notice stating –

(i) the amount of remuneration agreed under section 72E(2)(a) between the Director and the proprietor of the patent concerned named in the notice and, where applicable, the apportionment of the amount of remuneration under section 72E(5); and

(ii) that any other person who is entitled to claim remuneration payable under section 72E(2) may make an application to the court under section 72I(2); or

(b) a notice stating –

(i) the fact that the Director and the proprietor of the patent concerned named in the notice have failed to agree on the amount of remuneration payable under section 72E(2); and

(ii) that any other person who is entitled to claim remuneration payable under that section may make an application to the court under section 72I(2).

72G. Termination of import compulsory licences

(1) The Director may terminate an import compulsory licence by giving notice in writing to the import compulsory licensee if he is satisfied that any term or condition of the licence imposed under section 72C has been contravened.

(2) The Director shall as soon as practicable after the termination of an import compulsory licence under subsection (1) –

(a) give notice in writing to the proprietor of the patent concerned of the termination; and

(b) advertise in the official journal notice of the termination.

72H. No infringement of patents by persons to whom patented pharmaceutical products are disposed of in accordance with import compulsory licences

(1) A person to whom a patented pharmaceutical product is disposed of in accordance with an import compulsory licence may, without consent of the proprietor of the patent concerned, put on the market, stock or use the product, in Hong Kong, for the purposes in connection with the extreme urgency giving rise to the declaration under section 72B(1) as if he had been authorized by the licence to do so.

(2) A person to whom a patented pharmaceutical product is disposed of in accordance with an import compulsory licence shall not export or cause to export the product out of Hong Kong.

72I. References of disputes as to import compulsory licences

(1) If the Director and the proprietor of the patent concerned fail to agree on the amount of remuneration payable under section 72E(2), either party may, subject to subsection (5), apply to the court for an order to determine the amount of remuneration payable under that section.

(2) A person who is not a party to any agreement reached on the amount of remuneration under section 72E(2)(a) but is entitled to claim remuneration payable under section 72E(2) may, subject to subsection (5), apply to the court for an order for payment of remuneration under that section.

(3) In determining the appropriate amount of remuneration payable to the proprietor of the patent concerned, the court shall take into account all factors relevant to the circumstances, including –

(a) the economic value to Hong Kong of the use of the patented pharmaceutical product imported under the relevant import compulsory licence; and

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

(4) The total amount of remuneration determined by the court under subsection (3) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) may exceed the maximum amount of remuneration that may be agreed under section 72E(2)(a).

(5) No application may be made under subsection (1) or (2) after the expiry of the period of 28 days from the date of the advertisement of the notice under section 72F(2), unless the court determines otherwise.

(6) Any person aggrieved by –

(a) the grant of an import compulsory licence;

(b) any term or condition of an import compulsory licence imposed under section 72C;

(c) the apportionment of remuneration under section 72E(5); or

(d) the termination of an import compulsory licence under section 72G(1),

may, within 28 days after the date of the advertisement of the notice under section 72F(1)(b) or (2)(a)(i) or the date of the termination of the licence (as the case may be) or such further period as may be allowed by the court, apply to the court for a review of the grant of the licence, the terms or conditions of the licence, the apportionment of remuneration or the termination of the licence (as the case may be).

(7) In a review the court may –

(a) confirm, vary or cancel the import compulsory licence;

(b) confirm, vary or cancel a term or condition of the import compulsory licence imposed under section 72C;

(c) confirm or vary the apportionment of remuneration under section 72E(5);

(d) confirm or reverse the termination of the import compulsory licence under section 72G(1); or

(e) make any other order as the court thinks fit in the circumstances.

(8) The proprietor of the patent concerned may apply to the court for an order to terminate an import compulsory licence on the ground that any term or condition of the licence imposed under section 72C has been contravened.

(9) The court may, on an application under subsection (8) –

(a) make an order to terminate the import compulsory licence if the court is satisfied that any term or condition of the licence imposed under section 72C has been contravened; and

(b) make any other order as the court thinks fit in the circumstances.

PART IXB

EXPORT COMPULSORY LICENCES FOR PATENTED PHARMACEUTICAL PRODUCTS

72J. Interpretation of Part IXB

In this Part, unless the context otherwise requires –

"Director" (署長) means the Director of Health;

"export compulsory licence" (出口強制性特許) means a compulsory licence granted under section 72L;

"export compulsory licensee" (出口強制性特許持有人) means the holder of an export compulsory licence;

"Hong Kong patent number" (香港專利編號), in relation to a patent, means –

(a) a number assigned by the Registrar to a certificate issued in respect of the patent under section 27(1)(b);

(b) a number assigned by the Registrar to a certificate of grant issued in respect of the patent under section 118(2)(b); or

(c) a number assigned by the Registrar to a certificate of registration issued in respect of the patent under the Registration of Patents Ordinance (Cap. 42) which has been repealed under section 154(1);

"proprietor" (所有人), in relation to a patent, means the proprietor of the patent that is granted in Hong Kong.

72K. Application for export compulsory licences for patented pharmaceutical products

(1) At any time after the grant of a standard patent or a short-term patent in respect of a patented pharmaceutical product, any person may apply to the Director for the grant of an export compulsory licence under the patent concerned in relation to the product under section 72L.

(2) The application shall be made in writing and –

(a) shall specify the following information –

(i) the name and address of the applicant and of any agent or representative authorized by the applicant for the purpose of the application;

(ii) the name of the patented pharmaceutical product to be made and sold for export under an export compulsory licence the subject of the application;

(iii) the amount of the patented pharmaceutical product to be made and sold for export under the export compulsory licence;

(iv) the name of the eligible importing member to which the patented pharmaceutical product is to be exported under the export compulsory licence;

(v) the duration of the export compulsory licence applied for by the applicant;

(vi) the Hong Kong patent number or Hong Kong patent numbers in relation to the patented pharmaceutical product;

(vii) the proposed labelling, marking, packaging, colouring or shaping for the patented pharmaceutical product required by section 72M(1)(b)(ii);

(viii) the address of a website on which the applicant is required to post the information referred to in section 72M(1)(b)(iii);

(ix) any information obtained pursuant to subsection (3);

(x) any other information as the Director may reasonably require for the purposes of granting the export compulsory licence; and

(b) shall be accompanied by –

(i) a copy of the written request from the eligible importing member, any representative, non-governmental organization or international health organization authorized by the eligible importing member to the applicant for the patented pharmaceutical product and the amount of the product requested;

(ii) a copy of the notification made by the eligible importing member to the TRIPS Council stating –

(A) the name and the amount of the patented pharmaceutical product requested by the eligible importing member;

(B) where the eligible importing member is not a least-developed country recognized by the United Nations, that the eligible importing member has no or insufficient capacity to manufacture the patented pharmaceutical product; and

(C) where the pharmaceutical product is patented in the eligible importing member, that the eligible importing member has granted or intends to grant a compulsory licence to import the product in accordance with Article 31 bis in the Protocol and Article 31 of the TRIPS Agreement;

(iii) a copy of notice of the intended application given to the proprietor of the patent concerned under subsection (4)(b)(i) or (5)(a)(i);

(iv) where applicable, a declaration made by the applicant under the Oaths and Declarations Ordinance (Cap. 11) declaring that he has made reasonable efforts in accordance with subsection (4)(a) to obtain authorization from the proprietor of the patent concerned on reasonable commercial terms and conditions but the efforts have not been successful within 28 days after they had been made; and

(v) if the pharmaceutical product is patented in the eligible importing member, documentary evidence of any compulsory licence granted by the eligible importing member for importation of the product.

(3) A person who intends to make an application under subsection (1) shall, before he makes the application, take reasonable steps to obtain from the eligible importing member information on the amount of the patented pharmaceutical product to be made and exported to the eligible importing member by any exporting member other than Hong Kong under any compulsory licence granted elsewhere.

(4) Where a person intends to make an application under subsection (1) and the eligible importing member has not notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency, the person shall –

(a) not later than 28 days before the date of the application, make reasonable efforts to obtain authorization from the proprietor of the patent concerned on reasonable commercial terms and conditions to make and sell for export the patented pharmaceutical product of such amount as requested by the eligible importing member; and

(b) not later than 14 days before the date of the application –

(i) give the proprietor of the patent concerned notice of the intended application containing the information required under subsection (2)(a) (except subparagraphs (viii) and (x) of that subsection); and

(ii) attach to the notice all the documents and documentary evidence required under subsection (2)(b) (except subparagraphs (iii) and (iv) of that subsection).

(5) Where a person intends to make an application under subsection (1) and the eligible importing member has notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency, the person shall –

(a) (i) at any time before the application is made, give the proprietor of the patent concerned notice of the intended application containing the information required under subsection (2)(a) (except subparagraphs (viii) and (x) of that subsection); or

(ii) as soon as practicable after the application is made, give the proprietor of the patent concerned notice of the application containing the information required under subsection (2)(a);

(b) attach to the notice all the documents and documentary evidence required under subsection (2)(b) (except subparagraphs (iii) and (iv) of that subsection); and

(c) as soon as practicable after notice is given under paragraph (a), submit a copy of the notice to the Director.

72L. Grant of export compulsory licences for patented pharmaceutical products

The Director may grant an export compulsory licence under the patent concerned, subject to such terms and conditions as he may impose, to an applicant to make a patented pharmaceutical product and sell the product for export to an eligible importing member if he is satisfied that –

(a) all the requirements of section 72K have been met;

(b) the amount of the product applied for by the applicant to be made and sold for export under the licence does not exceed the amount stated in the notification referred to in section 72K(2)(b)(ii)(A), after taking into account any information obtained pursuant to section 72K(3); and

(c) the application is made in response to the request from the eligible importing member referred to in section 72K(2)(b)(i).

72M. Terms, conditions and nature of export compulsory licences

(1) The terms and conditions subject to which an export compulsory licence is granted under section 72L shall include –

(a) terms and conditions in respect of –

(i) the acts authorized to be done in relation to the patented pharmaceutical product under the licence;

(ii) the amount of the patented pharmaceutical product authorized to be made and sold for export under the licence;

(iii) the eligible importing member to which the patented pharmaceutical product is to be exported under the licence; and

(iv) the duration of the licence;

(b) terms and conditions providing that –

(i) the licence is non-assignable except with that part of the enterprise or goodwill

which enjoys the use of the patent under the licence;

(ii) the patented pharmaceutical product shall be –

(A) clearly identified as being made under the licence through specific labelling or marking; and

(B) distinguished from the same product made by or under authorization of the proprietor of the patent concerned through special packaging, colouring or shaping;

(iii) the export compulsory licensee shall, before shipment of the patented pharmaceutical product to the eligible importing member under the licence, post on the website maintained by or on behalf of the licensee or on the WTO website dedicated to and maintained for the purpose of Article 31 bis in the Protocol information in relation to –

(A) the amount of the patented pharmaceutical product that will be exported to the eligible importing member under the shipment; and

(B) the labelling, marking, packaging, colouring or shaping for the

patented pharmaceutical product required by subparagraph (ii);

(iv) the export compulsory licensee shall pay to the proprietor of the patent concerned such amount of remuneration as determined by the Director under section 72O(1) for the export compulsory licence in relation to the product;

(v) where there is more than one patent in relation to the patented pharmaceutical product, the export compulsory licensee shall apportion on an equal share basis among all the proprietors of the patents concerned the total amount of remuneration determined by the Director under section 72O(1);

(vi) subject to subparagraph (vii), the patented pharmaceutical product made under the licence shall be exported only to the eligible importing member specified in the licence; and

(vii) if the patented pharmaceutical product is also patented in the eligible importing member, the product shall be exported to the eligible importing member after it has granted a compulsory licence for importation of the product; and

(c) any other terms or conditions as the Director thinks fit.

(2) An export compulsory licence is non-exclusive.

72N. Notification of grant of export compulsory licences

The Director shall as soon as practicable after the grant of an export compulsory licence under section 72L –

(a) give notice in writing to the proprietor of the patent concerned, as identified pursuant to the information specified in the application in accordance with section 72K(2)(a)(vi), of the grant of the licence and its terms and conditions; and

(b) advertise in the official journal notice of the grant of the licence and its terms and conditions.

72O. Determination of remuneration payable to proprietors of patents

(1) The Director shall determine the amount of remuneration payable to the proprietor of the patent concerned under section 72M(1)(b)(iv).

(2) In determining the amount of remuneration, the Director shall take into account any advice given by the Director of Intellectual Property as regards the remuneration.

(3) The total amount of remuneration determined by the Director under subsection (1) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) shall not exceed 4% of the total purchase price for the product payable by the eligible importing member to the export compulsory licensee.

(4) The Secretary for Commerce, Industry and Technology may by notice published in the Gazette vary the percentage specified in subsection (3).

72P. Termination of export compulsory licences

(1) The Director may terminate an export compulsory licence by giving notice in writing to the export compulsory licensee if he is satisfied that –

(a) any term or condition of the licence imposed under section 72L has been contravened; or

(b) any information, document or documentary evidence specified in or accompanying the application in accordance with section 72K(2) is false, incorrect or incomplete in any material particular.

(2) The Director shall as soon as practicable after the termination of an export compulsory licence under subsection (1) –

(a) give notice in writing to the proprietor of the patent concerned, as identified pursuant to the information specified in the application in accordance with section 72K(2)(a)(vi), of the termination; and

(b) advertise in the official journal notice of the termination.

72Q. References of disputes as to export compulsory licences

(1) Any person aggrieved by –

(a) the grant of an export compulsory licence;

(b) any term or condition of an export compulsory licence imposed under section 72L; or

(c) the termination of an export compulsory licence under section 72P(1),

may, within 28 days after the date of the advertisement of the notice under section 72N(b) or the date of the termination of the licence (as the case may be) or such further period as may be allowed by the court, apply to the court for a review of the grant of the licence, the terms or conditions of the licence or the termination of the licence (as the case may be).

(2) In a review the court may –

(a) confirm, vary or cancel the export compulsory licence;

(b) confirm, vary or cancel a term or condition of the export compulsory licence imposed under section 72L;

(c) confirm or vary the determination of the amount of remuneration under section 72O(1);

(d) confirm or reverse the termination of the export compulsory licence under section 72P(1); or

(e) make any other order as the court thinks fit in the circumstances.

(3) In determining the appropriate amount of remuneration payable to the proprietor of the patent concerned, the court shall take into account all factors relevant to the circumstances, including –

(a) the economic value to the eligible importing member of the use of the patented pharmaceutical product exported to it under the relevant export compulsory licence; and

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

(4) The total amount of remuneration determined by the court under subsection (3) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical

product) may exceed the maximum amount of remuneration that may be determined by the Director under section 72O(1).

(5) The proprietor of the patent concerned may apply to the court for an order to terminate an export compulsory licence on the ground that –

(a) any term or condition of the licence imposed under section 72L has been contravened; or

(b) any information, document or documentary evidence specified in or accompanying the application in accordance with section 72K(2) is false, incorrect or incomplete in any material particular.

(6) The court may, on an application under subsection (5) –

(a) make an order to terminate the export compulsory licence if the court is satisfied that –

(i) any term or condition of the licence imposed under section 72L has been contravened; or

(ii) any information, document or documentary evidence specified in or accompanying the application in accordance with section 72K(2) is false, incorrect or incomplete in any material particular; and

(b) make any other order as the court thinks fit in the circumstances.

72R. Signature of documents by partnerships, companies and associations

For the purposes of this Part –

(a) a document signed for or on behalf of a firm shall be signed by all of its partners, by any partner stating that he signs on behalf of the firm or by any other person who satisfies the Director that he is authorized by the firm to sign the document;

(b) a document signed for or on behalf of a body corporate shall be signed by a director or the secretary or other principal officer of the body corporate or by any other person who satisfies the Director that he is authorized by the body corporate to sign the document; and

(c) a document signed for or on behalf of an unincorporated body or association of persons other than a firm shall be signed by any person who satisfies the Director that he is authorized by the unincorporated body or association of persons (as the case may be) to sign the document.".

6. Licences granted by order of the court or Registrar

(1) The heading of section 138 is amended by adding "**or by Director of Health**" after "**Registrar**".

(2) Section 138 is amended –

(a) by renumbering it as section 138(1);

(b) by adding –

"(2) Without prejudice to any other method of enforcement, any import compulsory licence or export compulsory licence granted under section 72C or 72L has effect as if it were a deed, executed by the proprietor of the standard patent or the short-term patent (as the case may be) and all other necessary parties.".

7. Section added

The following is added –

"**139A. Protection of Government and public officers**

(1) No liability shall rest on the Government or any public officer by reason of the fact that –

(a) any authority is given under section 69; or

(b) any import compulsory licence or export compulsory licence is granted under section 72C or 72L (as the case may be).

(2) A public officer is not personally liable in respect of any act or omission of his if it was done or made by him in the honest belief that it was required or authorized in the exercise of any function, duty or power of his under Part IX, IXA or IXB (as the case may be).

(3) The protection conferred on public officers by subsection (2) in respect of any act or omission does not affect any liability of the Government in tort for that act or omission.".

Explanatory Memorandum

The object of this Bill is to amend the Patents Ordinance (Cap. 514) ("the Ordinance") to implement the Protocol Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organisation to facilitate use of patented pharmaceutical products.

2. Clause 3 adds new definitions to section 2(1) of the Ordinance.

3. Clause 5 adds 2 new parts to the Ordinance. The proposed Part IXA governs the grant of import compulsory licences for patented pharmaceutical products and the proposed Part IXB governs the grant of export compulsory licences for patented pharmaceutical products.

4. The main provisions in the proposed Part IXA are –

(a) the proposed section 72B empowers the Chief Executive in Council to declare a period of extreme urgency for the purposes of applying provisions in relation to import compulsory licences in order to address any public health problem or threatened public health problem in Hong Kong;

(b) the proposed section 72C empowers the Director of Health ("Director") to grant an import compulsory licence, under certain circumstances, to a public officer or other person to import, put on the market, stock or use a patented pharmaceutical product or to do any other act in Hong Kong in relation to the product which would, but for the import compulsory licence, amount to an infringement of the patent concerned;

(c) the proposed section 72D provides for the terms and conditions to be imposed on import compulsory licences and the nature of the licences;

(d) the proposed section 72E –

  (i) provides for the payment of remuneration to the proprietor of the patent concerned by the Government under certain circumstances; and

  (ii) provides that the amount of remuneration is to be agreed between the Director and the proprietor of the patent concerned and the maximum amount of remuneration is to be agreed;

(e) the proposed section 72F requires the Director –

  (i) to notify the proprietor of the patent concerned and advertise in the official journal of the grant of the import compulsory licences and their terms and conditions; and

(ii) advertise in the official journal a notice in relation to the amount of remuneration agreed and apportioned and lodging of any claim of remuneration;

(f) the proposed section 72G provides that if any term or condition of an import compulsory licence has been contravened, the Director may terminate the licence;

(g) the proposed section 72H provides that persons to whom patented pharmaceutical products are disposed of in accordance with import compulsory licences may put on the market, stock or use the products under certain circumstances without infringing the patents concerned;

(h) the proposed section 72I empowers the Court of First Instance –

(i) to determine the amount of remuneration payable to the proprietor of the patent concerned in default of agreement between the Director and the proprietor of the patent concerned;

(ii) to determine any claim for remuneration made by the proprietor of the patent concerned who is not a party to any agreement reached on the amount of remuneration under section 72E(2)(a);

(iii) to review the grant of an import compulsory licence, including its terms and conditions, the apportionment of remuneration and termination of an import compulsory licence, by the Director; and

(iv) to terminate an import compulsory licence if any term or condition of the licence has been contravened.

5. The main provisions in the proposed Part IXB are –

(a) the proposed section 72K provides for application for an export compulsory licence and the requirements to be met;

(b) the proposed section 72L empowers the Director to grant an export compulsory licence, under certain circumstances, to make and sell a patented pharmaceutical product for export to an eligible importing member;

(c) the proposed section 72M provides for the terms and conditions to be imposed on export compulsory licences and the nature of the licences;

(d) the proposed section 72N requires the Director to notify the proprietor of the patent concerned and advertise in the official journal of the grant of the export compulsory licences and their terms and conditions;

(e) the proposed section 72O –

(i) provides that the Director shall determine the amount of remuneration payable to the proprietor of the patent concerned by the export compulsory licensee; and

(ii) provides that the maximum amount of remuneration is to be determined by the Director;

(f) the proposed section 72P provides that if any term or condition of an export compulsory licence has been contravened or the applicant supplies false information, the Director may terminate the licence;

(g) the proposed section 72Q empowers the Court of First Instance –

(i) to review the grant of an export compulsory licence, including its terms and conditions, and

termination of an export compulsory licence, by the Director;

(ii) to review the determination of the amount of remuneration payable to the proprietor of the patent concerned; and

(iii) to terminate an export compulsory licence if any term or condition of the licence has been contravened or the applicant supplies false information;

(h) the proposed section 72R makes provision for signature of documents by partnerships, companies and associations.

6. Clauses 4 and 6 are consequential amendments.

7. Clause 7 adds a new section 139A to the Ordinance to protect the Government and public officers from certain liability in relation to Government use of patents or grant of import compulsory licences or export compulsory licences under Part IX, IXA or IXB of the Ordinance.

Annex B

Chapter:	514	PATENTS ORDINANCE	Gazette Number	Version Date
Section:	2	Interpretation	L.N. 40 of 2004	07/05/2004

(1) In this Ordinance, unless the context otherwise requires-

"application for a patent" (專利的申請) means an application for a standard patent or an application for a short-term patent;

"court" (法院) means the Court of First Instance; (Amended 25 of 1998 s. 2)

"date of filing" (提交日期)-

(a) in relation to a request to record or a request for registration and grant, means the date which is the date of filing that request by virtue of section 17 or 24 respectively;

(b) in relation to an application for a standard patent has the meaning specified in relation to that term in section 3(ii);

(c) in relation to a designated patent application, means the date specified as such in the designated patent application;

"employee" (僱員) means a person who works or (where the employment has ceased) worked under a contract of employment (whether with the Government or with any other person);

"employer" (僱主), in relation to an employee, means the person by whom the employee is or was employed;

"exclusive licence" (專用特許) means a licence from the proprietor of or applicant for a patent conferring on the licensee, or on him and persons authorized by him, to the exclusion of all other persons (including the proprietor or applicant), any right in respect of the invention to which the patent or application for a patent relates, and "exclusive licensee" (專用特許持有人) and "non-exclusive licence" (非專用特許) shall be construed accordingly;

"international application" (國際申請) means an international application for a patent made under the Patent Cooperation Treaty;

"International Bureau" (國際局) means the International Bureau of Intellectual Property provided for under the Convention Establishing the World Intellectual Property Organization signed at Stockholm on 14 July 1967;

"law of the designated patent office" (指定專利當局的法律) means-

(a) in relation to a designated patent office established under the law of any

country, territory or area other than Hong Kong, the law of that country, territory or area;

(b) in relation to a designated patent office established under an international agreement, the provisions of the international agreement;

"mortgage" (按揭) when used as a noun, includes a charge for securing money or money's worth and, when used as a verb, shall be construed accordingly;

"non-prejudicial disclosure" (不具損害性的披露) means, in relation to an invention, a disclosure of the invention which is not to be taken into consideration for the purposes of determining whether or not the invention forms part of the state of the art;

"official journal" (官方公報) means the publication for the time being specified under section 150A as the official journal of record; (Added 2 of 2001 s. 2)

"opposition or revocation proceedings" (反對或撤銷專利的法律程序) means, in relation to a designated patent, proceedings under the law of the designated patent office providing for the revocation or amendment of the designated patent within a specified period after the grant;

"Paris Convention" (《巴黎公約》) means the Convention for the Protection of Industrial Property signed at Paris on 20 March 1883, as revised or amended from time to time; (Amended 2 of 2001 s. 2)

"Paris Convention country" (巴黎公約國) means-

(a) any country for the time being specified in Schedule 1 as being a country which has acceded to the Paris Convention;

(b) any territory or area subject to the authority or under the suzerainty of any country specified in Schedule 1 pursuant to paragraph (a), or any territory or area administered by any such country, on behalf of which such country has acceded to the Paris Convention;

"patent application" (專利申請) has the same meaning as an application for a patent;

"Patent Cooperation Treaty" (《專利合作條約》) means the treaty of that name done at Washington on 19 June 1970, as revised or amended from time to time; (Amended 2 of 2001 s. 2)

"patented invention" (專利發明) means an invention for which a standard patent or, as the case may be, a short-term patent is granted and "patented process" (專利方法) shall be construed accordingly;

"patented product" (專利產品) means-

(a) a product which is an invention for which a standard patent or a short-term patent (as the case may be) has been granted;

(b) in relation to a process for which a standard patent or a short-term patent (as the case may be) has been granted, a product obtained directly by means of the process or to which the process has been applied;

"prescribed" (訂明) means prescribed or provided for by rules made under section 149;

"protected layout-design (topography)" (受保護的布圖設計(拓撲圖)) has the meaning assigned to that term by section 2(1) of the Layout-design (Topography) of Integrated Circuits Ordinance (Cap 445);

"register" (註冊紀錄冊、註冊)-

(a) as a noun, means the register of patents kept under section 51; and

(b) as a verb, means, in relation to any thing, to register or register particulars, or enter notice of that thing in the register and, in relation to a person, means to enter his name in the register,

and cognate expressions shall be construed accordingly;

"Registrar" (處長) means the Registrar of Patents;

"Registrar of Patents" (專利註冊處處長) means the person holding that office by virtue of the Director of Intellectual Property (Establishment) Ordinance (Cap 412);

"registry" (註冊處) means the Patents Registry administered by the Registrar;

"request for registration and grant" (註冊與批予請求) means a request under section 23 for the registration of a designated patent and the grant of a standard patent for the invention shown in the published specification of the designated patent;

"request to record" (記錄請求) means a request under section 15 to record a designated patent application;

"right" (權利), in relation to any patent or patent application, includes an interest in the patent or application and, without prejudice to the foregoing, any reference to a right in a patent includes a reference to a share in the patent;

"rules" (規則) means rules made by the Registrar under section 149;

"short-term patent" (短期專利) means a patent for an invention granted under Part XV;

"short-term patent application" (短期專利申請) means an application under Part XV for a short-term patent;

"specification"' (說明書), in relation to an application for a patent under this Ordinance, a designated patent application or an international application, means the description, claims and drawings contained in the application;

"standard patent" (標準專利) means a patent for an invention granted under Part II;

"standard patent application" (標準專利申請) means an application under Part II for a standard patent;

"verified copy" (核實副本) means, in relation to a document, a copy verified in the prescribed manner;

"World Trade Organisation Agreement" (《世界貿易組織協議》) means the agreement of that name done at Marrakesh in 1994, as revised or amended from time to time; (Amended 2 of 2001 s. 2)

"WTO member country, territory or area" (世界貿易組織成員國、地區或地方) means

any country, territory or area for the time being specified in Schedule 1 as being a country, territory or area which has acceded to the World Trade Organisation Agreement.

(2) The expressions listed in the left-hand column below are defined in, or fall to be construed in accordance with, the provisions of this Ordinance listed in the right-hand column in relation to those expressions.

Expression	Relevant Provision
Application for a standard patent (標準專利的申請)	section 3
Corresponding designated patent (相應指定專利)	section 4
Corresponding designated patent application (相應指定專利申請)	section 4
Deemed date of filing (當作提交日期)	section 38
Designated patent (指定專利)	section 4
Designated patent application (指定專利申請)	section 4
Divisional designated patent application (指定專利的分開申請)	section 22(1)
Government use (政府徵用)	section 69(2)
Paris Convention country (巴黎公約國)	section 98(6)
Patent (專利)	section 6(1)
Published (發表)	section 5
Work (實施)	section 6(4)

Where there are in effect 2 or more patents for the same invention, any use of the invention which does not constitute an infringement of any one such patent (whether by virtue of consent given by the proprietor, a compulsory licence having effect under Part VIII or the provisions of Part IX relating to Government use) shall not constitute an infringement of the other such patent.

Chapter:	514	PATENTS ORDINANCE	Gazette Number	Version Date

Section:	138	Licences granted by order of the court or Registrar		30/06/1997

Any order for the grant of a licence under section 14, 56, 64 or 65 shall, without prejudice to any other method of enforcement, have effect as if it were a deed, executed by the proprietor of the standard patent and all other necessary parties, granting a licence in accordance with the order.

[cf. 1977 c. 37 s. 108 U.K.]

Economic Implications

The proposals in the Bill balance the importance of patent protection (for promoting research and development of new pharmaceutical products) against the need to facilitate access to pharmaceutical products (for addressing public health problems). The introduction of the proposed compulsory licensing system is consistent with Hong Kong's commitment to having a robust intellectual property protection system.

2. The Bill would provide a framework for local generic medicine manufacturers to produce and export pharmaceutical products to other WTO Members. As Hong Kong does not at present have a strong production base for generic medicines, the immediate benefit to the local generic medicine industry would be minimal.

Financial and Civil Service Implications

3. We envisage that the chance of triggering the Protocol is likely to be remote. The additional administrative costs, if any, for the Department of Health, Intellectual Property Department and the Customs and Excise Department to implement the Protocol are expected to be minimal and will be absorbed within their existing resources.

4. In the event that Hong Kong applies the system under the Protocol as an Exporting Member, the licensee to whom the Government has granted an export compulsory licence (to manufacture and sell for export a patented pharmaceutical product) has to pay adequate remuneration to the proprietor of the patent concerned. The Government has no obligation to pay remuneration if the licensee fails to pay the proprietor of the patent.

5. In the event that Hong Kong applies the system under the Protocol as an Importing Member, the Government may have to pay remuneration to the local proprietor of the patent under the exceptional circumstances set out in paragraph 17 of the Legislative Council Brief. It is not possible to estimate at this stage the amount of remuneration which may need to be paid by the Government. This will depend on such factors as the nature of the public health problem and the quantum of the medicine in demand, but the commitment is expected to be one-off in nature.

6. We do not intend to impose a fee for issuing the import and export compulsory licences. As the chance for triggering the licensing system is likely to be remote, the revenue foregone, if any, should be negligible.

Sustainability Implications

7. The proposals in the Bill will enable Hong Kong to have a wider choice of supply of medicines to address a public health crisis under extreme urgency. It is therefore conducive to the sustainability principle of pursuing policies which promote and protect the physical health and safety of the people of Hong Kong.