For discussion on
19 December 2006

Legislative Council Panel on Commerce and Industry

Proposed Amendments to the Patents Ordinance to Implement a Protocol which amends the Agreement on Trade-related Aspects of Intellectual Property Rights

Purpose

This paper presents the Administration's proposal to amend the Patents Ordinance to implement a Protocol which is open to acceptance by Members of the World Trade Organization ("WTO"). By amending the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") of the WTO, the Protocol facilitates access to generic versions of patented drugs when addressing public health problems. A copy of the Protocol is at Annex 1.

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The TRIPS Agreement

2. The TRIPS Agreement contains provisions governing the protection of patent. A patent holder has various exclusive rights including the rights 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 would need to obtain prior authorisation from the patent holder, or else he renders himself liable to civil action.

3. Under Article 31 of the TRIPS Agreement, a WTO Member may issue a compulsory licence allowing a third party to use the subject matter of a patent without the authorisation of the right holder provided certain conditions are met. One of the conditions is that the use shall be *predominantly* for the supply of the domestic market of the WTO Member authorising such use (Article 31(f)). In order words, the majority of the product should not be exported. Another condition is that the patent holder has to be paid *adequate remuneration* in the circumstances of each case, taking into account the economic value of

the use under authorisation (Article 31(h)).

Historical background to the Protocol

4. In November 2001, the Ministerial Conference of the WTO in Doha adopted the Declaration on the TRIPS Agreement and Public Health. This "Doha Declaration" 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. It also recognised that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of the compulsory licensing system under the existing TRIPS Agreement. More specifically, they could not appeal to other economies with manufacturing capacity to export generic versions of the product to them. The TRIPS Council of the WTO was tasked to work out a solution to this problem.

5. In August 2003, the General Council of the WTO adopted a decision which temporarily waives the obligations set out in Article 31(f) and Article 31(h) 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 contained in Article 31(f) which requires that the predominant part should be for domestic use, to another WTO Member lacking production capacity. It also avoids double remuneration by providing that 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.

6. On 6 December 2005, the General Council of the WTO adopted the Protocol which would, subject to paragraph 7 below, replace the temporary waiver and give permanent effect to the arrangements conceived at the Doha Declaration.

7. 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.

Use of the system under the Protocol to import pharmaceutical product

8. After the adoption of the Doha Declaration, some developed economies contended that use of the system to address the problem recognised in the Declaration should only be confined to the least-developed economies and low-income developing economies. In the event, 11 developing economies[1] including Hong Kong agreed not to take advantage of the system as importer unless in situations of national emergency or other circumstances of extreme urgency.

The Proposed Legislative Amendments

9. Hong Kong played a constructive role in the WTO discussions leading to the promulgation of the Protocol. The Administration intends to notify the WTO of Hong Kong's acceptance of the Protocol before 1 December 2007.

10. Our existing Patents Ordinance provides for a compulsory licensing framework modelled on Article 31 of the TRIPS Agreement. To implement the Protocol, we will need to amend our domestic patent legislation.

Hong Kong as an Importing Member

11. As stated in paragraph 8 above, Hong Kong will only use the framework provided in the Protocol to import pharmaceutical product in situations of emergency or other circumstances of extreme urgency. 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 or threatened public health problem. This formulation is in line with the existing section 68 of the Patents Ordinance which relates to the use by the government of patented inventions in general in circumstances of extreme urgency.

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[1] The following economies have declared to the WTO they would use the system as importers only in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates.

12. During such a period of extreme urgency, if the Director of Health ("the Director") is satisfied that Hong Kong has insufficient or no manufacturing capacity to manufacture a certain pharmaceutical product to address the public health problem in question, Hong Kong may use the system under the Protocol to import the product. The Director may, notwithstanding any patents granted in Hong Kong in respect of such pharmaceutical product, grant a compulsory licence to any person to import, use, and distribute etc., the pharmaceutical product, without the consent of the patent holder. The Director should notify the patent holder of the grant of compulsory licence as soon as practicable.

13. In line with the requirements in the Protocol, the compulsory licence should be subject to the following conditions -

(a) it should only cover such quantity of pharmaceutical product as is necessary to meet the public health needs of Hong Kong in connection with the urgency giving rise to the declaration in paragraph 11 above;

(b) the entire quantity of the pharmaceutical product should only be used in Hong Kong, but not for export to other places; and

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

In addition, the compulsory licence should be subject to such other requirements as the Director considers appropriate having regard to the public health needs in Hong Kong giving rise to the declaration of extreme urgency in the first place. Failure to comply with the licensing conditions may lead to termination of the licence.

14. The Protocol specifically sets out that there is no need to pay remuneration at the Importing Member's end if adequate remuneration is paid at the Exporting Member's end. Hence, there is no need to pay remuneration to the holder of the patent in Hong Kong

unless adequate remuneration had not been paid at the Exporting Member's end.

15. We propose that any party aggrieved by the decision of the Director following the grant of the compulsory licence may appeal to the Court of First Instance. The Court may by order vary or cancel the licence or make such order on such terms as it thinks fit.

Hong Kong as an Exporting Member

16. Hong Kong may also make use of the system under the Protocol to export generic versions of patented pharmaceutical products in specified circumstances. If a WTO Member indicates that it intends to avail itself of the Protocol to source a certain pharmaceutical product, any local manufacturer who considers that he has the capacity to manufacture the product may, subject to the issue of a compulsory licence by the Government, make use of the system under the Protocol to manufacture and export the product to the concerned Importing Member.

17. We propose that the Director be empowered to issue such compulsory licences. For cases where the importing WTO Member does not declare that it is under national emergency or other circumstances of extreme urgency, an applicant for a compulsory licence to export should, before applying for such a licence, make reasonable efforts to obtain an authorisation from the patent holder on reasonable commercial terms and conditions. The Director would only consider granting the compulsory licence if the applicant has failed to obtain the authorisation within 28 days. On receiving the application, the Director would also give the patent holder an opportunity to comment on the application provided the latter could be located with reasonable efforts within a reasonable period. However, for cases where the importing WTO Member is under national emergency or other circumstances of extreme urgency, the foregoing requirements would not apply.

18. When granting a compulsory licence, the Director may attach to it terms and conditions he deems appropriate, including but not limited to the following –

(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 product so produced should be specifically labelled/ marked to facilitate easy identification; and

(c) the licensee shall before shipment of the product, post on a designated website :
(i) the quantities of the product supplied to the Importing Member and
(ii) the distinguishing feature of the label/ marking of the product.

Failure to comply with any of the terms and conditions may lead to termination of the licence.

19. According to the Protocol, there is an obligation on the part of the Exporting Member to pay adequate remuneration to the patent holder, taking into account the economic value of the use of the pharmaceutical product (the subject of the compulsory licence) to the Importing Member. When considering the amount of remuneration to be paid by the licensee, we have drawn reference from other jurisdictions which have notified the WTO of the acceptance of the Protocol, or have made/are making legislation or measures to implement the Protocol. As we understand it, Mainland China will determine the remuneration to be paid on a case-by-case basis, whereas the European Community, Canada and Switzerland have prescribed, or are considering to prescribe, a maximum rate or a formula for calculating the amount of remuneration for most of the circumstances (the amount generally does not exceed a level equivalent to 4% of the total price to be paid by the Importing Member for the product). Details of the mechanisms for determining the rate of remuneration in these jurisdictions are set out in Annex 2.

20. The system has not been used by any WTO Member before. Only a limited number of jurisdictions have put in place a mechanism to implement the system. We consider it appropriate to leave flexibility in determining the amount of remuneration payable to the patent holder under the law. Hence, we do not propose to prescribe a formula in the Patents Ordinance. The amount of remuneration will be determined on a

case-by-case basis, but it would not exceed 4% of the total price to be paid by the Importing Member to the Hong Kong manufacturer. The Government will continue to keep international developments in view and consider the appropriate remuneration to be paid in the light of the circumstances of the case when a compulsory licence has to be granted.

21. We also propose that any party aggrieved by the decision of the Director or the remuneration following the grant of compulsory licence, or the rejection of an application may appeal to the Court of First Instance. The Court may by order vary or cancel the licence or make such order on such terms as it thinks fit.

Consultation

22. We have consulted the relevant stakeholders on the proposed amendments, 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 organizations concerned with the public health problems afflicting the developing countries.

23. The views received and the preliminary response of the Administration are summarised at Annex 3.

The Next Step

24. We are drafting the necessary legislative amendments. We plan to introduce the Amendment Bill into the Legislative Council in the first half of 2007.

Advice sought

25. Members are invited to give views on the proposals as set out in paragraphs 9 to 21 above. We will take Members' views into account when preparing the proposed legislative amendments.

Commerce and Industry Branch
Commerce, Industry and Technology Bureau
December 2006

Annex 1

WORLD TRADE ORGANIZATION

WT/L/641
8 December 2005

(05-5842)

AMENDMENT OF THE TRIPS AGREEMENT

Decision of 6 December 2005

The General Council;

Having regard to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;

Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

Noting the consensus to submit this proposed amendment to the Members for acceptance;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.

2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

ATTACHMENT

PROTOCOL AMENDING THE TRIPS AGREEMENT

Members of the World Trade Organization;

Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Hereby agree as follows:

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31*bis* after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.

3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.

6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Article 31bis

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31*bis* and this Annex:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[1];

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[2] to the Council for TRIPS of its intention to use the system set out in Article 31*bis* and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members[3] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31*bis* are that:

(a) the eligible importing Member(s)[4] has made a notification[2] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[5];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31*bis* of this Agreement and the provisions of this Annex[6];

(b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:

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[1] This subparagraph is without prejudice to subparagraph 1(b).

[2] It is understood that this notification does not need to be approved by a WTO body in order to use the system.

[3] Australia, Canada, the European Communities with, for the purposes of Article 31*bis* and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

[4] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31*bis* on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

[5] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

[6] This subparagraph is without prejudice to Article 66.1 of this Agreement.

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[7] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify[8] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[9] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31*bis* should be promoted. To this end, developed country

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[7] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to the system.

[8] It is understood that this notification does not need to be approved by a WTO body in order to use the system.

[9] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

or

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

Annex 2

Royalty arrangement of other WTO Members when acting as an exporting party
(as at 5 December 2006)

WTO Member	Royalty Arrangement
European Union[1]	✦ The relevant European Community Regulation does not prescribe how to calculate the remuneration but states that the remuneration shall be a maximum of 4% of the total price to be paid by the importing WTO member for the pharmaceutical product for cases of national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use. ✦ For other circumstances, the remuneration shall be determined taking into account the economic value of the use to the importing member, and humanitarian and non-commercial circumstances relating to the issuance of the compulsory licence.
Canada	✦ Remuneration payable is calculated in accordance with a prescribed formula taking into account the humanitarian and non-commercial basis for the grant of licence. ✦ The formula comprises a mathematical calculation depending on the importing member's rank on the United Nations Human Development Index (UNHDI)[2]. The lower the ranking of the importing member on the UNHDI, the lower would be the royalty rate to be paid. ✦ The formula is as follows – $\frac{1+ \text{no. of countries on UNHDI} - \text{member's rank on UNHDI}}{\text{no. of countries on UNHDI}} \times 0.04 = \text{royalty rate}$ ✦ The formula cannot mathematically result in a royalty rate in excess of 4 percent which the Canadian Government considers consistent with humanitarian and non-commercial considerations that are the foundation of Canada's access to medical regime under the Doha Declaration in August 2003.

[1] The related legislation, EC Regulation No. 816/2006 (Article 10) is binding on all EU members. There are 25 members at the moment: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, the Netherlands, United Kingdom.

[2] An index to measure human development across nations.

WTO Member	Royalty Arrangement
Switzerland	✦ Proposing legislative amendment to its patents law to implement WTO's decision to help needy WTO members with their public health problem. ✦ The draft law provides for the remuneration to be determined according to the economic value of the licence in the importing member and the development level of that member. The Canada formula is being considered, and the mode of calculation will be specified through regulation. ✦ According to the proposed formula, the lowest eligible member currently on the Index would attract a royalty rate of 0.02% while the theoretical maximum would be 4%.
Mainland	✦ The relevant order promulgated by the State Intellectual Property Office only stipulates that reasonable remuneration is to be paid to the patent proprietor. There is no description on how to work out a reasonable remuneration; it may have to be dealt with on a case-by-case basis.

Annex 3

Summary of Feedback from Consultees
(As at 11 December 2006)

Consultee	View / Comment	The Administration's preliminary response
Hong Kong Association of the Pharmaceutical Industry	✦ agree that in the case of Hong Kong as an exporting member, that the amount of remuneration for the compulsory licence be determined on a case-by-case basis; but request removal of the 4% maximum cap for this amount ✦ request to see the actual wording of the final Bill prior to submission to LegCo	✦ We consider a cap appropriate, taking into account the humanitarian and non-commercial considerations underlying the promulgation of the Protocol.
Asian Patent Attorney Association Hong Kong Group	✦ the maximum cap on remuneration (in the case of Hong Kong as an exporting member) is too low ✦ consideration be given to raising the cap in case the importing member is not under national emergency or extreme urgency	✦ The cap is currently pitched at 4% of the total price to be paid by the importing member for the pharmaceutical product concerned. In arriving at such a figure, we have taken into account the current thinking in overseas countries including the EU, Canada and Switzerland. In the light of future international developments, we may re-visit the propriety of pitching the cap at 4%.

Consultee	View / Comment	The Administration's preliminary response
Medecins Sans Frontieres	✦ it is positive that it is the Director of Health who will be making the decision to import a generic version of a patented medicine under a compulsory license, although this will only happen after the CE-in-Council has declared a period of extreme urgency ✦ it is positive that in cases where prior negotiations are required between the patent holder and an interested Hong Kong generic manufacturer, the proposal sets a period of 28 days for negotiation to avoid undue delay ✦ it is positive to set a 4% maximum cap for remuneration in case of exports under a compulsory licence to avoid abuse ✦ it is a pity that there is no simplified and accelerated procedure to vary the quantity of medicine to be manufactured and exported under the proposed system	✦ We will examine the need for provisions that would allow such an accelerated procedure.
Chinese University of Hong Kong	✦ strongly support the proposal	

Consultee	View / Comment	The Administration's preliminary response
Law Society of Hong Kong	✦ no comment on the proposal	
The Hong Kong Institute of Trade Mark Practitioners	✦ generally support the proposal, in particular that Hong Kong would be able to import medicine under the Protocol in times of extreme emergency. ✦ need more time to seek its members' views on the 4% maximum cap for remuneration in the case of Hong Kong as an exporting member	
The University of Hong Kong	✦ generally support the proposal ✦ consider that the Protocol would not affect the University's academic activities or result in any negative impact on industry technology transfer ✦ consider it important to have appropriate rules and regulations in place for the Director of Health to issue compulsory licences	
Versitech Limited (A technology transfer arm of the University of Hong Kong)	✦ has made some observations on the implementation details (e.g. How to make payment to the patent holder when Hong Kong is an exporting member)	

Consultee	View / Comment	The Administration's preliminary response
	✦ will further assess the implications of the proposal on a local patent holder or the University of Hong Kong when details of the legal provisions are available	