Bills Committee on the Patents (Amendment) Bill 2007
The Administration's response to points raised in the Assistant Legal Adviser's letter dated 7.5.07

Item	Section	Observations made by the Assistant Legal Advisor (ALA)	The Administration's response
1	72H(1)	Explain why subsection (b) in s.72C {i.e. *any other act which would, apart from s.72C, amount to an infringement of the patent concerned*} is not included in s.72H(1).	(i) The import compulsory licensing system would only be triggered to address a public health problem when Hong Kong is in a situation of extreme urgency. S.72C(a) is intended to cover all major acts (which would otherwise be patent infringing) that the licence holders might need to take for sourcing and supplying the patented pharmaceutical product. S.72C(b) aims to encompass all possible incidental acts that may be necessary or expedient in connection with the extreme urgency giving rise to the declaration under section 72B. This provides added flexibility to the Director of Health (DH) in issuing import compulsory licences in situations of extreme urgency. (ii) The licence holder may not always be the party that supplies the patented pharmaceutical product direct to patients. Other parties involved in the supply chain such as pharmaceutical retailers, hospitals and clinics ("subsequent recipients") may commit patent infringing acts (e.g. selling or stocking the product) in supplying the product to patients. The law should exempt these subsequent recipients from liability for such acts as are necessary or expedient for distribution of the pharmaceutical product to, or for use in treatment of patients in Hong Kong in connection with the extreme urgency. We believe that their acts in dealing with the products are limited to (a) putting the products on the market, (b) stocking the products, or (c) using the products in treatment of patients. Reference has been drawn to the prohibition of use of invention under sections 73 and 74 of the Patents Ordinance. (iii) Subsequent recipients may involve a large group of persons along the supply chain. They are not holders of the compulsory licence. Hence,

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			the scope of the exemption should not be too wide. Otherwise, it may cause concern to the proprietor of the patent. (iv) In view of the above, we do not consider it appropriate to include a subsection like 72C(b) in s.72(H).
2	72H(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 (which shall be a term and condition of the import compulsory licence under the proposed s.72D). Confirm whether other terms and conditions of the import compulsory licence are also applicable to the person to whom a patented pharmaceutical product is disposed of.	(i) The persons to whom a patented pharmaceutical product is disposed of are not the holders of the import compulsory licence. Hence, they are not subject to the terms and conditions of the licence. (ii) The Protocol Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organisation requires the importing WTO Members to take reasonable measures to prevent re-exportation of the pharmaceutical products that have been imported into their territories under the Protocol. The reason for including s.72H(2) is to provide a clear indication to the persons to whom the pharmaceutical product is disposed of in accordance with the import compulsory licence that they should not re-export the patented pharmaceutical product in question. Though there are no sanctions for violation of this subsection under the Patents Ordinance, it should be noted that no export licence would be issued under the Import and Export Ordinance (Cap. 60) to any person who intends to re-export to another place a pharmaceutical product which have been imported into Hong Kong under the import compulsory licence. Any person who exports such a product without a valid export licence under Cap. 60 renders himself liable under that Ordinance.
3	72I(2)	Give examples of the type of persons under the proposed s.72I(2) who is not a party to any agreement reached on the	There may be more than one patent in relation to a patented pharmaceutical product and therefore more than one patent proprietor. If a person (though not being a party to the agreement reached in the first

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		amount of remuneration under the proposed s.72E(2)(a) but is entitled to claim remuneration payable under the proposed section s.72E(2).	place on the amount of remuneration) could establish himself to be a patent proprietor of such patented pharmaceutical product, he may apply to the court for an order for payment of remuneration under s.72I(2).
4	72I(6)	Any person aggrieved by any of the matters under subparagraphs (a) to (d) may, within 28 days after the date of the advertisement of the notice under the proposed s.72F(1)(b) or 2(a)(i) or the date of the termination of the licence or such further period as may be allowed by the court, apply to the court for a review. It is noted that the date of the termination of the licence is used for the scenario in s.72I(6)(d) instead of the date of the advertisement of the notice under the proposed s.72G(2)(b). Please elaborate the rationale behind this arrangement.	Under section 72I(6)(d), the party aggrieved by the DH's decision to revoke a licence is likely the licensee in question. S.72G(1) stipulates that if the DH decides to terminate a licence, such as where any conditions of the import compulsory licence are not complied with, he will inform the licensee by giving a notice. The licensee should be well aware of the decision of the termination and hence the date of the termination of the licence is used as the starting point for calculating the 28-day period. This would enable the licence holder to refer the case immediately to the court for review if he is aggrieved by the DH's decision to terminate his licence. The licensee could do it without having to wait for DH to publish his decision in the official journal. On the other hand, a person who is aggrieved by the DH's decision to grant an import compulsory licence, the terms and conditions of the licence, or the apportionment of the amount of remuneration may not necessarily be the applicant for the licence or the proprietor of the patent concerned. Hence, the aggrieved party may not be aware of DH's decision until he/she has seen the advertisement. It is therefore considered more appropriate to use the date of the advertisement as the starting point for calculating the 28-day period.
5	72K(2)(b)(iii)	According to the proposed s.72K(2)(b)(iii), it is a mandatory requirement for an application for an export compulsory licence to be accompanied by a copy of notice of the intended application given to	(i) Where an eligible importing member has notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency, the person who intends to make an application for an export compulsory licence should be left with the flexibility to notify the proprietor of the patent concerned of his application before or after the

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		the proprietor of the patent concerned under the proposed subsection (4)(b)(i) or 5(a)(i). However, it appears that there is a third possibility under the proposed subsection (5)(a)(ii) for the applicant to give the proprietor of the patent concerned notice of the application as soon as practicable after the application is made (where the eligible importing member has notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency). In such circumstances, the applicant would not be able to comply with the mandatory requirement under the proposed section 72K(2)(b)(iii). Please explain the difference in arrangement.	application is made having regard to the circumstances of the case. This enables expeditious actions to be taken to source the patented pharmaceutical product for use by the eligible importing member to arrest a public health crisis. (ii) The requirement for an application for an export compulsory licence to be accompanied by a copy of notice of the intended application given to the proprietor of the patent concerned under s.72K(2)(b)(iii) only applies when (a) the eligible importing member has not notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency (i.e., where s.72K(4)(b)(i) applies); or (b) when the eligible importing member has notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency **and** the applicant has notified the proprietor of the patent concerned before the application is made (i.e., where s.72K(5)(a)(i) applies). (iii) Our intention is that when the eligible importing member has notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency **and** the applicant has chosen to notify the proprietor of the patent concerned after the application is made (i.e., where s.72K(5)(a)(ii) applies), the requirement under s.72K(2)(b)(iii) does not apply. (iv) In the light of ALA's observations, we suggest adding "where applicable," to the beginning of s.72K(2)(b)(iii) to put our intention beyond doubt.
6	72N	Unlike the situation for an import compulsory licence {under the proposed s.72F(2)}, there is no requirement on DH	(i) S.72N(2)(b) stipulates that DH shall as soon as practicable after the grant of an export compulsory licence under s.72L advertise in the official journal notice of the grant of the licence and its terms and conditions. In

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		to advertise in the official journal a notice in relation to the amount of remuneration in respect of an export compulsory licence under the proposed s.72N. Please elaborate the rationale behind this arrangement.	S.72M(1)(b)(iv), one of the terms and conditions is that the export compulsory licensee shall pay to the proprietor of the patent concerned such amount of remuneration as determined by the DH under s. 72O(1) for the export compulsory licence in relation to the product. Hence, the notice advertised in the official journal under s.72N should contain the amount of remuneration in respect of an export compulsory licence. (ii) It should be noted that when Hong Kong is using the Protocol to import a pharmaceutical product, 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. This situation, if it ever arises, would probably occur long after the licence has been issued. 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. In the light of the foregoing, the amount of remuneration to be paid would not form a licence condition. Section 72F(2) expressly requires that DH shall advertise such information in the official journal so that any aggrieved person may refer the case to the court.
7	72Q	Under the proposed s.72Q(1), any person aggrieved by any of the matters under subparagraph (a) to (c) may, within 28 days after the date of the advertisement of the notice under the proposed s.72N(b) or the date of the termination of licence or such further period as may be allowed by	Please see our response in item 4 above.

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		the court, apply to the court for a review. It is noted that the date of the termination of the licence is used in the scenario in s.72Q(1)(c) instead of the date of the advertisement of the notice under the proposed s.72P(2)(b). Please elaborate the rationale behind this arrangement.	