立法會
Legislative Council

LC Paper No. CB(1)1894/06-07
(These minutes have been seen by the Administration)

Ref : CB1/BC/2/06

Bills Committee on
Patents (Amendment) Bill 2007

Minutes of second meeting on
Tuesday, 22 May 2007, at 8:30 am
in the Conference Room B of the Legislative Council Building

Members present	**:**	Hon SIN Chung-kai, JP (Chairman) Hon Margaret NG Hon LI Kwok-ying, MH, JP Hon WONG Ting-kwong, BBS
Public Officers attending	**:**	Commerce, Industry and Technology Bureau Mr Christopher K B WONG Deputy Secretary for Commerce, Industry and Technology (Commerce and Industry) Ms Priscilla TO Principal Assistant Secretary for Commerce, Industry and Technology (Commerce and Industry) Mr T W MAK Assistant Secretary for Commerce, Industry and Technology (Commerce and Industry) Intellectual Property Department Mr Peter CHEUNG Deputy Director of Intellectual Property Ms Lavinia Y M CHANG Assistant Director of Intellectual Property (Ag.)

Department of Justice

Ms Carmen CHU
Senior Government Counsel

Ms Amy W Y CHAN
Government Counsel

Department of Health

Dr Cindy LAI
Assistant Director of Health

Clerk in attendance : Miss Erin TSANG
Chief Council Secretary (1)3

Staff in attendance : Mr Timothy TSO
Assistant Legal Adviser 2

Mrs Mary TANG
Senior Council Secretary (1)2

Ms YUE Tin-po
Senior Council Secretary (1)5

Action

I. Confirmation of minutes of meeting

(LC Paper No. CB(1)1633/06-07 -- Minutes of meeting on 4 May 2007)

The minutes of the meeting held on 4 May 2007 were confirmed.

II. Meeting with the Administration

(LC Paper No. CB(3)451/06-07 -- The Bill

LC Paper No. CB(1)1634/06-07(01) -- Marked-up copy of the Bill prepared by the Legal Service Division

Ref: CIB CR 06/08/11 -- The Legislative Council Brief on "Patents (Amendment) Bill 2007" issued by the Commerce, Industry and Technology Bureau

LC Paper No. LS53/06-07	--	The Legal Service Division Report
LC Paper No. CB(1)1634/06-07(02)	--	Background brief prepared by the Legislative Council Secretariat
LC Paper No. CB(1)1634/06-07(03)	--	Letter dated 7 May 2007 from the Assistant Legal Adviser to the Administration)

2. The Committee deliberated (index of proceedings attached at **Appendix**).

Admin 3. The Chairman requested the Administration to provide a written response to the Assistant Legal Adviser's letter dated 7 May 2007 for the Bills Committee's consideration at the next meeting.

(*Post-meeting note*: The Administration's response was circulated to the Bills Committee on 1 June 2007 vide LC Paper No. CB(1)1813/06-07.)

Meeting arrangements

4. The Chairman reminded members that as agreed at the first meeting on 4 May 2007, the next meeting of the Bills Committee would be held on 21 June 2007 at 2:30 pm to meet with deputations and the Administration. He advised that the Bills Committee might also proceed to commence clause-by-clause examination of the Bill after meeting with deputations at the next meeting.

5. Members agreed that the fourth meeting of the Bills Committee would be held on Friday, 20 July 2007, at 2:30 pm.

III. Any other business

6. There being no other business, the meeting ended at 9:25 am.

Council Business Division 1
Legislative Council Secretariat
13 June 2007

Appendix

Proceedings of second meeting of the
Bills Committee on
Patents (Amendment) Bill 2007
on Tuesday, 22 May 2007, at 8:30 am
in Conference Room B of the Legislative Council Building

Time marker	Speaker	Subject(s)	Action required
000000 – 000159	Chairman	Confirmation of minutes of the meeting held on 4 May 2007 (LC Paper No. CB(1)1633/06-07)	
000160 – 000957	Chairman Administration	The Administration's briefing on Patents (Amendment) Bill 2007 (the Bill): (a) Historical background to the Protocol which aimed to facilitate access to generic versions of patented pharmaceutical products for addressing public health problems. In essence, the General Council of the World Trade Organization (WTO) decided in August 2003 to temporarily waive the obligations set out in Article 31(f) and Article 31(h) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the WTO in specified circumstances. In effect, pharmaceutical products made under compulsory licences in one WTO Member could be exported to another WTO Member lacking production capacity, without the restriction of Article 31(f) which stipulated that the majority of the product made under a compulsory licence should be predominantly for the supply of the domestic market and should not be used for export. Moreover, double remuneration could also be avoided as no remuneration was required to be paid in the WTO Member which imported the product if adequate remuneration had already been paid pursuant to Article 31(h) in the WTO Member which exported a pharmaceutical	

Time marker	Speaker	Subject(s)	Action required
		product. In December 2005, the General Council of the WTO further adopted the Protocol which would replace the temporary waiver and give permanent effect to the above arrangements, and the Protocol would take effect if it was ratified by two thirds of the WTO Members by 1 December 2007 or such later date as might be decided by the Ministerial Conference of the WTO. (b) Since the existing provisions of the Patents Ordinance (Cap. 514) which provided for a compulsory licensing framework was modelled on Article 31 of the TRIPS Agreement, it had to be amended before Hong Kong could implement and make use of the Protocol. In this connection, while some WTO Members (mainly the developed economies like the United States) had indicated that they would not use the system under the Protocol to import pharmaceutical products, Hong Kong, together with some other WTO Members such as Israel, Singapore and Korea, had declared that they would only use the system as an importer in situations of national emergency or other circumstances of extreme urgency. (c) The Administration intended to notify the WTO of Hong Kong's ratification of the Protocol after the passage of the Bill. (d) Under the Bill, it was proposed that during such a period of extreme urgency, if the Director of Health (the DH) was satisfied that Hong Kong had insufficient or no manufacturing capacity to manufacture a certain pharmaceutical product to address the public health problem in question, he	

Time marker	Speaker	Subject(s)	Action required
		might grant an import compulsory licence to any person to import, use, put on market or stock the pharmaceutical product. In line with the Protocol, the import compulsory licence would be subject to certain requirements, such that the entire quantity of the product imported under the licence should be for use in Hong Kong only (i.e. should not be exported to other places), and the product should be clearly identified, through specific labeling or marking, as being produced pursuant to the Protocol, etc. (e) Likewise, as an Exporting Member, Hong Kong might also make use of the system under the Protocol if a WTO Member indicated that it intended to avail itself of the Protocol to source a certain pharmaceutical product. Any local manufacturer might, subject to the issue of export compulsory licence by the DH, make and export the product to the concerned Importing Member. (f) On remuneration to be paid to the patent holder, there was no need for Hong Kong as an Importing Member to pay remuneration to the patent holder as the remuneration should be paid at the Exporting Member's end. However, to cater for extremely rare circumstances where remuneration had not been paid at the exporting end even after all legal remedies for recovery of such payment of the remuneration had been exhausted at the exporting end, it was proposed that the Government would have to pay the remuneration to the patent holder in Hong Kong, and the amount of remuneration would be agreed between the patent holder and the DH on the advice of the Director of Intellectual Property (DIP).	

Time marker	Speaker	Subject(s)	Action required
		(g) Similarly, the holder of an export compulsory licence granted in Hong Kong should pay remuneration to the local patent holder. The amount should be determined on a case-by-case basis by the DH on the advice of DIP, and the amount would not exceed a level equivalent to 4% of the total price to be paid by the importer for the product. (h) Any person aggrieved by the DH's decision in relation to the grant of compulsory licences or the amount of remuneration determined by the DH might apply to the court for review.	
000958 – 001702	Chairman Administration	The Chairman's enquiry on why the proposed local legal framework had to be put in place before the Protocol was to be ratified by WTO Members by 1 December 2007 but not vice versa. The Administration explained that the General Council of the WTO had already made a decision to temporarily waive the obligations set out in Articles 31(f) and (h). The adoption of the Protocol was therefore a further step aiming to give permanent effect to the arrangements as set out under the temporary waiver. If the Bill was passed, Hong Kong could then notify the WTO Secretariat of its ratification of the Protocol with the relevant legal framework in place for implementation of it. The Chairman's further enquiry on the possible consequences if the Protocol was not ratified by two thirds of WTO Members by 1 December 2007. The Administration advised that the deadline for acceptance of the Protocol might be extended beyond 1 December 2007 to allow	

Time marker	Speaker	Subject(s)	Action required
		more time for WTO Members to indicate their acceptance of the Protocol. Currently, many WTO Members were already working on their relevant patents laws in order to implement the Protocol.	
001703 – 002659	Chairman Mr LI Kwok-ying Ms Margaret NG Mr WONG Ting-kwong Administration	Mr LI Kwok-ying enquired whether there was restriction for exporting the generic medicines to other places, say the Mainland, if those places were also suffering from the same public health problem. The Administration's advice that- (a) Pursuant to the Protocol, the entire quantity of the pharmaceutical product so imported should not be used for export to other places. As such, under proposed section 72D(1)(b)(i) of the Bill, it was proposed that the patented pharmaceutical product which was imported to Hong Kong under the import compulsory licence should not be exported out of Hong Kong, say, by the importer. Moreover, under the Import and Export Ordinance (Cap.60), any person who exported pharmaceutical products out of Hong Kong without a valid export licence issued by the DH would be liable to criminal sanctions. (b) In the case of end-users, pursuant to proposed section 72H(2) of the Bill, it was proposed that any person to whom a patent pharmaceutical product was disposed of in accordance with an import compulsory licence should not export or cause to export the product out of Hong Kong. As such, any end-user of the product who, without the valid licence from the DH, exported or caused to export the product out of Hong Kong would also be liable to criminal sanctions. Nevertheless, the	

Time marker	Speaker	Subject(s)	Action required
		enforcement actions to be taken would depend on the circumstances involved in each case. (c) Concerning the Mainland, as it had already promulgated relevant order for implementation of the Protocol, it could also avail itself of the Protocol to source the necessary pharmaceutical product in case of public health problems. Discussion of possible scenarios in which proposed section 72H(2) might or might not apply.	
002700 – 004027	Chairman Mr WONG Ting-kwong Administration	Mr WONG Ting-kwong's concern about the enactment of the Bill in relation to the Protocol which might not be able to take effect if it was eventually not ratified by two thirds of the WTO Members, and hence the futility of the present exercise in amending the local patents legislation. The Administration's advice that – (a) WTO Members had already expressed their good faith in recognizing the gravity of public health problems afflicting many developing and least-developed countries, and hence their decision in August 2003 to temporarily waive the obligations as set out in Articles 31(f) and (h) of the TRIPS Agreement to facilitate especially developing and least-developed economies' access to generic medicines, as well as their further adoption of the Protocol in December 2005 with a view to giving permanent effect to the arrangements under the temporary waiver. (b) So far, seven WTO Members, including the US and Switzerland, had notified acceptance of the Protocol with the	

Time marker	Speaker	Subject(s)	Action required
		WTO Secretariat. (c) On the need for the present exercise to amend the Patents Ordinance, Hong Kong had to discharge its role as a responsible Member of WTO in concert with the international community. In addition, the Administration saw enactment of the Amendment Bill and the acceptance of the Protocol a positive step that would help strengthen Hong Kong's capability in protecting public health. Even if the Protocol was not ratified by two thirds of the WTO Members by 1 December 2007, the deadline for acceptance was likely to be extended by the Ministerial Conference of the WTO. Under such circumstances, Hong Kong could still ride on the temporary waiver and, by means of the legal framework put in place, avail itself of the arrangements to import generic medicines from other WTO Members, for addressing a public health problem in situations of extreme urgency. Relative to the existing provisions in the Patents Ordinance, the new provisions would give Hong Kong added flexibility in sourcing pharmaceutical products to contain a public health crisis. The temporary waiver, already in operation since 2003, reflected the prevailing legal norms accepted by the international community. Mr WONG Ting-kwong asked whether Hong Kong was the first WTO Member which had commenced the legislative exercise for implementation of the Protocol. The Administration clarified that some WTO Members such as Canada had already put in place legislation for implementation of the Protocol some time ago.	

Time marker	Speaker	Subject(s)	Action required
		In view of the fact that it was necessary to adapt the local patents legislation if only to implement the temporary waiver decided by the WTO in 2003, the Chairman enquired why the Bill was not introduced to the Legislative Council for scrutiny earlier. The Administration explained that Hong Kong was amongst the first batch of WTO economies undertaking the relevant legislative exercise for implementation of the Protocol.	
004028 – 004531	Chairman Administration	The Chairman enquired whether Hong Kong had to complete the legislative exercise and make available the relevant legislative framework before it could notify the WTO Secretariat of its ratification of the Protocol. The Administration explained that legal backing was called for before Hong Kong was in the position to notify the WTO of its ratification of the Protocol.	
004532 – 004738	Chairman Administration	The Chairman's enquiry on the criteria for granting of export compulsory licences for patented pharmaceutical products. The Administration explained that if a WTO Member indicated that it intended to avail itself of the Protocol to source a certain pharmaceutical product, any local manufacturer which had the manufacturing capacity could apply to the DH for the grant of an export compulsory licence to make and export the product to the WTO Member concerned.	
004739 – 004955	Chairman Administration	Meeting arrangements	The Administration to follow up as stated in paragraph 3 of the minutes.

Council Business Division 1
Legislative Council Secretariat
13 June 2007