

立法會
Legislative Council

LC Paper No. CB(1)2368/06-07
(These minutes have been seen
by the Administration)

Ref: CB1/BC/2/06

**Bills Committee on
Patents (Amendment) Bill 2007**

**Minutes of fourth meeting on
Thursday, 19 July 2007, at 10:45 am
in Conference Room B of the Legislative Council Building**

Members present : Hon SIN Chung-kai, JP (Chairman)
Hon Margaret NG
Hon WONG Ting-kwong, BBS

Members absent : Hon LI Kwok-ying, MH, JP

Public Officers attending : Commerce and Economic Development Bureau

Mr Christopher K B WONG
Deputy Secretary for Commerce and Economic Development
(Commerce and Industry)

Mr T W MAK
Assistant Secretary for Commerce and Economic
Development (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

Mr Anthony CHAN
Chief Pharmacist

Mr Ronald M K LAM
Principal Medical & Health Officer

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)2141/06-07 -- Minutes of meeting held on 21 June 2007)

The minutes of the meeting held on 21 June 2007 were confirmed.

- II. Papers issued since last meeting**
(LC Paper No. CB(1)1998/06-07(01) -- Administration's response to submissions from Médecins Sans Frontieres Hong Kong and the Democratic Party)

LC Paper No. CB(1)2077/06-07(01) -- Submission dated 6 July 2007
(*English version only*) from the Hong Kong Association
of the Pharmaceutical Industry)

2. Members noted that the above papers had been issued for the Bills Committee's information since the last meeting held on 21 June 2007.

III. Meeting with the Administration
Clause-by-clause examination of the Bill

(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

LC Paper No. CB(1)1813/06-07(01) -- Administration's response to
points raised in the Assistant
Legal Adviser's letter dated 7 May
2007

LC Paper No. CB(1)2142/06-07(01) -- Administration's response to
issues raised at the Bills
Committee meeting on 21 June
2007

LC Paper No. LS102/06-07 -- Paper on issues raised at the Bills
Committee meeting on 21 June
2007 prepared by the Legal
Service Division

LC Paper No. CB(1)2156/06-07(01) -- Administration's response to submissions from Médecins Sans Frontieres Hong Kong, the Democratic Party and the Hong Kong Bar Association)

3. The Bills Committee deliberated (Index of proceedings attached at **Appendix**).

Proposed section 72E(2)

Admin 4. The Administration advised that as the Director of Health (DH) was the licensing authority for import and export compulsory licences under the Bill, it would move Committee Stage Amendments (CSAs) to amend section 72E(2) so that the word "Government" where it first appeared would be replaced with "the Director". As it would be for the Government to pay the remuneration, it was not necessary to change the reference to "Government" where it subsequently appeared in the provision.

Proposed sections 72I and 72Q

Admin 5. In examining the proposed sections 72I and 72Q which empowered the court to handle disputes as to import/export compulsory licences, Ms Margaret NG was concerned that the proposed provisions, as currently drafted, did not spell out in a definitive manner the factors and the basis on which the amount of remuneration should be worked out for reference by the court when determining the amount of remuneration payable to the proprietor of the patent concerned. She was of the view that since the court was not an administrative tribunal and the mission of the court was to execute the law, the aforementioned factors and basis should be clearly spelt out in law to provide a legal basis for decisions made by the court in relation to the determination of the amount of remuneration. As such, she suggested that the Administration should consider revising the drafting of the proposed provisions to specify, say, by way of subsidiary legislation in this respect, and to define the scope of evidence, such as evidence provided by expert witnesses, which could be put to the court for consideration, as well as to provide more definitive guidelines for the court to follow when determining the amount of remuneration. In response, the Administration advised that in addition to the evidence given by DH and the Director of Intellectual Property (or, for that matter, any expert witness they might call up) and making reference to the rate prescribed for calculating the amount of remuneration with respect to prevailing international standards, the court would take into account all factors relevant to the circumstances, including those specified under proposed sections 72I(3) and 72Q(3). At the request of the Chairman, the Administration undertook to consider whether the drafting of the proposed sections 72I and 72Q could be further improved, in the light of Ms NG's observations.

6. In this connection, the Bills Committee noted that the provisions of Orders in the Rules of the High Court (RHC) and the inherent jurisdiction of the High Court applied to the proceedings under the Patents Ordinance (Cap. 514). As such, the procedures for applications under proposed sections 72I and 72Q would be provided in the RHC, and the Administration would submit its proposals for consideration by the High Court's Rules Committee in due course. In this regard, Ms Margaret NG requested the Administration to consult the views of the Hong Kong Bar Association and the Law Society of Hong Kong on the procedures for applications, such as whether it should be by way of application, summons or originating motions, etc, and who would be empowered to make rules under the proposed provisions, etc, before submitting proposals to the High Court's Rules Committee for consideration. The Administration advised that the procedures for applications under proposed sections 72I and 72Q were being examined and would be provided under Order 103 of RHC. The Administration assured Ms NG that the Hong Kong Bar Association and the Law Society of Hong Kong would be consulted on the abovementioned procedures. The Chairman requested the Administration to report to the Bills Committee the outcome of the consultation before the Bills Committee reported its deliberations to the House Committee.

Admin

Proposed section 72I(6)

7. Members noted that under proposed section 72I(6), any person aggrieved by any of the matters under paragraphs (a) to (d) might, within 28 days after the date of the advertisement of the notice under proposed section 72F(1)(b) or (2)(a)(i) or the date of the termination of the licence or such further period as might be allowed by the court, apply to the court for a review. As the person aggrieved by DH's decision to terminate the licence might not be the licensee himself, and hence had to get known of such decision via the advertisement published in the official journal under the proposed section 72G(2)(b), which was only published as soon as practicable, but not immediately, by DH, the aggrieved person might in fact have less than 28 days for applying to the court for a review. On the principle of equity and fairness, the Bills Committee considered that the date of the advertisement of the notice of termination under proposed section 72G(2)(b) should instead be used as the starting point for calculating the 28-day period. The Administration took note of the Bills Committee's concerns, and undertook to re-assess the appropriateness of using the date of the termination of the licence in the proposed section 72I(6). If necessary, the Administration would consider improving the drafting of proposed section 72I(6) to ensure that any party, apart from the licensee, aggrieved by the termination of the licence, would be given 28 days to apply to the court for a review and the starting point for calculating the 28-day period would be from the date when the notice of termination was advertised on the official journal under proposed section 72G(2)(b) so as to tie in with the policy intention that sufficient time would be given to aggrieved parties for lodging of review.

Admin

Proposed section 72K

Admin 8. Noting that proposed section 72K mainly covered the information to be provided to support the application made to DH for the grant of an export compulsory licence, the Chairman suggested that standard statutory forms should be provided to facilitate local manufacturers to make such application in a timely manner, taking into account that it might be time critical for the application to be approved as the Importing Member might be faced with national emergency or other circumstances of extreme urgency which required urgent sourcing of the concerned pharmaceutical product to address the crisis. To address the Chairman's concern, the Administration undertook to explore feasible administrative arrangements such as publication of guidance note, etc, so as to facilitate local manufacturers in making such applications to DH for consideration. At the request of the Chairman, the Administration also undertook to advise the Bills Committee of its decision and relevant details in due course.

9. In this connection, the Administration explained that 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 proposed section 72K(2)(b)(iii) only applied when (a) the eligible Importing Member had not notified the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) that it was faced with a national emergency or other circumstances of extreme urgency (i.e. where proposed section 72K(4)(b)(i) applied); or (b) when the eligible Importing Member had notified the TRIPS Council that it was faced with a national emergency or other circumstances of extreme urgency **and** the applicant had notified the proprietor of the patent concerned before the application was made (i.e. where proposed section 72K(5)(a)(i) applied). As such, when the eligible Importing Member had notified the TRIPS Council that it was faced with a national emergency or other circumstances of extreme urgency **and** the applicant had chosen to notify the proprietor of the patent concerned **after** the application was made (i.e. where proposed section 72K(5)(a)(ii) applied), the requirement under proposed section 72K(2)(b)(iii) did not apply. In order to put beyond doubt such policy intention, the Administration would move CSA to add "where applicable" to the beginning of proposed section 72K(2)(b)(iii).

Disposal of the remaining stock of patented pharmaceutical product

Admin 10. In relation to the Bills Committee's concern as to how the business interests of the traders importing and supplying the patented pharmaceutical product could be safeguarded when the extreme urgency leading to the declaration under proposed section 72B(1) was over and there was remaining stock of the product, the Administration advised that it was exploring if specific provisions should be introduced into the Bill to enable the Government to accept the remaining stock surrendered by the licence holders in return for payment at cost by the Government. In this respect, the Administration also took members through the

possible scenarios on how the remaining stock of the concerned product would be handled (i.e. paragraphs 11 to 15 of the Administration's written response (LC Paper No. CB(1)2142/06-07(01))).

Amendment of the title of the "Secretary for Commerce, Industry and Technology"

- Admin 11. The Administration advised that it would make CSAs to amend the title of the "Secretary for Commerce, Industry and Technology" as stated in clause 2, proposed sections 72E(6) and 72O(4) in clause 5 of the Bill arising from the passage of resolution under section 54A of the Interpretation and General Clauses Ordinance (Cap.1) to reshuffle the statutory functions and amend the titles of the Directors of Bureaux.

Other proposed CSAs

- Admin 12. The Administration advised that it would also propose CSAs to the relevant proposed provisions to clarify its policy intention and address deputations' concerns as stated in items 3.3, 3.6(vi) and 4.3(ii) and (iv) of its respective tabulated responses to the submissions of the Hong Kong Bar Association and the Hong Kong Association of the Pharmaceutical Industry (i.e. LC Paper No. CB(1)2156/06-07(01), and LC Paper No. CB(1)2191/06-07 issued on 24 July 2007).

Arrangements for the next meeting

- Admin 13. The Bills Committee completed clause by clause examination of the Bill. The Chairman reminded members that the next meeting would be held on 19 September 2007, at 2:30pm. In this connection, the Administration was requested to follow up the outstanding issues as stated in the above paragraphs and to revert to the Bills Committee. The Chairman also requested the Administration to forward the full set of the proposed CSAs to the Secretariat for onward consideration by the Bills Committee at the next meeting. Subject to the CSAs being in order, the Bills Committee would report to the House Committee recommending the Second Reading Debate on the Bill.

IV. Any other business

14. There being no other business, the meeting ended at 12:20 pm.

**Proceedings of fourth meeting of
Bills Committee on
Patents (Amendment) Bill 2007
on Thursday, 19 July 2007, at 10:45 am
in Conference Room B of the Legislative Council Building**

Time marker	Speaker	Subject(s)	Action required
000000 – 000520	Chairman	<p>Confirmation of minutes of the meeting held on 21 June 2007 (LC Paper No. CB(1)2141/06-07)</p> <p>Members noted the papers issued since the last meeting held on 21 June 2007</p>	
000521 – 001924	Chairman Ms Margaret NG Administration	<p>Discussion of the operation of proposed sections 72I and 72Q on the determining of the amount of remuneration by the court</p> <p>Discussion of the rules of procedures of the High Court which applied to the proceedings under the Patents Ordinance</p>	The Administration to follow up as stated in paragraphs 5 and 6 of the minutes
001925 – 002910	Chairman Administration	<p>The Administration's briefing on its written response to issues raised at the Bills Committee meeting on 21 June 2007, such as the disposal of the remaining stock of patented pharmaceutical product (LC Paper No. CB(1)2142/06-07(01)).</p> <p>The Chairman's enquiry as to how the local patent proprietor could prove to the Director of Health (DH) that remuneration had not been paid to the patent proprietor at the Exporting Member's end after the exhaustion of all legal remedies there</p> <p>The Administration's advice that -</p> <p>(a) pursuant to the Protocol adopted by the General Council of the World Trade Organization (WTO) in December 2005, there was no need for Hong Kong as an Importing Member to pay remuneration to the patent proprietor as the remuneration should have already been paid at the Exporting Member's end. Nevertheless, under extreme circumstances, such as where the manufacturer at the Exporting</p>	The Administration to follow up as stated in paragraphs 4 and 10 of the minutes

Time marker	Speaker	Subject(s)	Action required
		<p>Member's end went bankrupt and could not pay the remuneration, DH might have to determine the amount of remuneration to be paid to the patent proprietor on the advice of the Director of Intellectual Property. In this regard, DH would assess the information tendered by the local proprietor, such as direct/indirect verbal or written information and circumstantial evidence.</p> <p>(b) with global patent ownership, local patent proprietor might request the Exporting Member's end to check with the patents registry concerned to verify and prove to DH whether remuneration had been paid to the patent proprietor at the Exporting Member's end.</p>	
002911 – 003200	Chairman ALA2	ALA2's briefing on the Legal Service Division's paper on issues raised at the Bills Committee meeting on 21 June 2007 (LS102/06-07)	
003201 – 004448	Chairman Administration	The Administration's briefing on its respective written responses to submissions from the Hong Kong Bar Association and the Hong Kong Association of the Pharmaceutical Industry (i.e. LC Paper No. CB(1)2156/06-07(01), and LC Paper No. CB(1)2191/06-07 issued on 24 July 2007)	The Administration to follow up as stated in paragraph 12 of the minutes
004449 – 013004	Chairman ALA2 Administration Mr WONG Ting-kwong	<p>Clause-by-clause examination of the Bill <u>Clause 5 – Parts IXA and IXB added (namely, 72A, 72B, 72C, 72D, 72E, 72F, 72G 72H, 72I, 72J, 72K, 72L, 72M, 72N, 72O, 72P, 72Q and 72R)</u></p> <p>ALA2's briefing on his letter to the Administration dated 7 May 2007 in relation to proposed sections 72H, 72I, 72K(2)(b)(iii), 72N and 72Q (LC Paper No. CB(1)1634/06-07(03)) and the Administration's response to points raised in his letter (LC Paper No. CB(1)1813/06-07(01))</p>	The Administration to follow up as stated in paragraphs 7, 8, 9 and 11 of the minutes

Time marker	Speaker	Subject(s)	Action required
		<p>The Chairman's enquiry as to whether sanctions would be imposed on violation of proposed section 72H(2)</p> <p>The Administration advised that there were no sanctions imposed under proposed section 72H(2). Nevertheless, any person who, without a valid export compulsory licence issued by the Department of Health, exported or caused to export the patented pharmaceutical product out of Hong Kong would be liable to criminal sanctions under the Import and Export Ordinance (Cap. 60). As such, the Administration stressed that although no sanctions were imposed under the proposed 72H(2) on a person for exporting or causing to export the concerned pharmaceutical product out of Hong Kong, the situation could be dealt with under the existing mechanism, i.e. sanctions would be imposed under the Import and Export Ordinance for such act.</p> <p>Noting that the patented pharmaceutical product imported to Hong Kong under the import compulsory licence should be distinguished from the same product made by or under authorization of the proprietor of the patent concerned through, inter alia, special packaging, ALA2 enquired whether the person to whom a patented pharmaceutical product was disposed of in accordance with an import compulsory licence under proposed section 72H could change the packaging of the product for the purpose of sale without entailing any sanctions to be imposed on them.</p> <p>The Administration advised that all patented pharmaceutical products had to be registered with the Pharmacy and Poisons Board before they could be sold in Hong Kong. Change of the packaging of the products after registration would not be allowed, and the sale of such products was tantamount to the selling of unregistered products which was in breach of the law and would be liable to sanctions.</p>	

Time marker	Speaker	Subject(s)	Action required
		<p>The Administration explained that the proposed section 72I provided that disputes in relation to import compulsory licences would be dealt with by the court. Discussion on the appropriateness of using the date of the advertisement of the notice on the termination of an import compulsory licence as starting point for calculating the 28-day period in the scenario under proposed 72I(6)(d)</p> <p>Members raised no query on proposed section 72J</p> <p>Discussion on whether standard statutory forms for application for export compulsory licences for patented pharmaceutical products would be provided under proposed section 72K</p> <p>In relation to proposed section 72K(2)(a)(x) which stipulated that the local manufacturer applying for an export compulsory licence should provide any other information as the Director might reasonably require for the purpose of granting such licence, Mr WONG Ting-kwong asked and the Administration explained that this provision was to cater for unforeseeable circumstances which made the provision of information other than those covered in proposed section 72K(2)(a)(i) to (ix) necessary. The Administration assured that DH would exercise his power provided in this provision in a reasonable manner and the information so requested from applicants (i.e. local manufacturers) would only be those necessary for the purpose of granting the export compulsory licence.</p> <p>In relation to proposed section 72K(4)(a), the Chairman noted that the local manufacturer wishing to apply for an export compulsory licence should, not later than 28 days before the date of the application, make reasonable efforts to obtain authorization from the concerned patent proprietor on reasonable commercial terms and conditions to make and sell for export the concerned pharmaceutical product.</p>	

Time marker	Speaker	Subject(s)	Action required
		<p>He considered that the 28-day requirement for making the abovementioned arrangement a bit lengthy. In response, the Administration explained that the 28-day requirement only applied when the eligible Importing Member had <u>not</u> notified the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) that it was faced with a national emergency. In other words, such requirement only applied under non-emergency situation.</p> <p>In response to the Chairman's enquiry, the Administration explained that "TRIPS Council" as mentioned in proposed section 72K and the rest of the proposed sections referred to the Council for Trade-Related Aspects of Intellectual Property Rights, and such interpretation had already been provided for in clause 3 of the Bill.</p> <p>Regarding the phrase "eligible importing member" as appeared in proposed section 72L and other proposed sections of the Bill, the Chairman enquired and the Administration advised that notifications made by intending importing members (the interpretation of the phrase "eligible importing member" was provided in clause 3 of the Bill) would be listed and uploaded on the dedicated WTO webpage.</p> <p>Regarding proposed section 72M(1)(b)(i), Mr WONG Ting-kwong noted that the export compulsory licence was non-assignable, except with that part of the enterprise or goodwill which enjoyed the use of the patent under the licence. He enquired whether DH, when imposing terms and conditions under this proposed section with respect to the export compulsory licence, would take into consideration circumstances that the shareholding situation of the licensee to which the export compulsory licence was issued might change and hence the licence holder was no longer the original one which had applied to and been issued with such licence by DH. The Administration explained that change of</p>	

Time marker	Speaker	Subject(s)	Action required
		<p>shareholding was a commercial activity which would not be taken into account by DH when determining the terms and conditions of the compulsory export licence. DH would only consider revoking the licence if the body corporate (法人團體) i.e. the licensee, was not fulfilling the terms and conditions so imposed.</p> <p>Mr WONG Ting-kwong noted that proposed section 72P(1)(b) stipulated that DH might terminate the export compulsory licence if any information, document, or documentary evidence specified in or accompanying the application was false, incorrect or incomplete. While agreeing that DH should terminate the licence if the applicant provided false information in his application, he considered that flexibility should be exercised on cases when the information provided by the applicant was just incorrect or incomplete as such situations could be rectified by providing supplementary information, etc. The Administration advised that DH <u>might</u> (as opposed to "should") terminate the export compulsory licence if he was satisfied, inter alia, that any information, document or documentary evidence specified in or accompanying the application in accordance with section 72K(2) was false, incorrect or incomplete in any material particular. The Administration also stressed that <u>DH could exercise discretion not to terminate</u> the licence if considered appropriate, such as where supplementary information could be provided by the licensee to rectify mistakes so made.</p>	
013005 – 013056	Chairman Administration	<p><u>Clause 6 - Licences granted by order of the court or Registrar</u></p> <p>Members raised no query</p>	

Time marker	Speaker	Subject(s)	Action required
013057 – 013332	Chairman ALA2 Administration	<u>Clause 7 - Section added ("Protection of Government and public officers")</u> Discussion of possible scenarios in which proposed section 139(A)(3) might apply. In gist, ALA and the Administration explained in response to the Chairman's enquiry that notwithstanding the protection provided to public officers under proposed section 139(A)(2) to the effect that they were not liable for any act or omission if this was done or made in the honest belief that it was required or authorized in the exercise of any function, duty or power under Part IX, IXA or IXB, the Government might still be liable in tort for that act or omission.	
013333 – 013435	Chairman Administration	Arrangements for the next meeting	The Administration to follow up as stated in paragraph 13 of the minutes