# 立法會
# *Legislative Council*

LC Paper No. CB(1)2141/06-07
(These minutes have been seen by the Administration)

Ref: CB1/BC/2/06

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

**Minutes of third meeting on**
**Thursday, 21 June 2007, at 2:30 pm**
**in Conference Room A of the Legislative Council Building**

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

**Attendance by invitation** : The Hong Kong Association of the Pharmaceutical Industry

Dr Anthony CHAN
Vice President

Ms Sabrina CHAN
Executive Director

Democratic Party

Mr Mark LI
Deputy Spokesman of Health Policy

**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

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Action

**I. Confirmation of minutes of meeting**

(LC Paper No. CB(1)1894/06-07 -- Minutes of meeting held on 22 May 2007)

The minutes of the meeting held on 22 May 2007 were confirmed.

**II. Meeting with deputations and the Administration**

Meeting with deputations

1. The Hong Kong Association of the Pharmaceutical Industry
(LC Paper No. CB(1) /06-07(01) -- Submission)

2. Democratic Party
(LC Paper No. CB(1)1908/06-07(01) -- Submission)

Submissions from organizations not attend the meeting

1. Médecins Sans Frontieres Hong Kong
(LC Paper No. CB(1)1908/06-07(02) -- Submission)

2. The Law Society of Hong Kong
(LC Paper No. CB(1)1908/06-07(03) -- Submission)

3. Hong Kong Bar Association
(LC Paper No. CB(1)1944/06-07(01) -- Submission)

*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)

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

3. On disputes with respect to the grant of import/export compulsory licences, the Administration advised that a mechanism had already been put in place for the court to handle disputes relating to "Government use" of patents during a period of extreme urgency under existing sections 68 and 72 of the Patents Ordinance (Cap. 514) (PO). In this connection, the Bills Committee requested the Administration to clarify the nature of the review by the court under the proposed sections 72I and 72Q, and to provide information on the operation of the proposed provisions , including the related rules of procedures applicable to the proceedings concerned, and related court cases under the existing Patents Ordinance. Ms Margaret NG also requested the Administration to provide information on similar provisions in other ordinances in which the concerned parties could also apply to the court for a review, as well as determination of payment of a monetary amount in default of agreement between the parties, as in the case of the proposed section 72I.

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(*Post-meeting note*: The information provided by the Administration was circulated to the Bills Committee on 17 July 2007 vide LC Paper No. CB(1)2142/06-07(01).)

Admin 4. The Administration was requested to provide a detailed written response to all submissions provided by the deputations, including those which had not attended the meeting.

(*Post-meeting note*: The Administration's response to deputations' views was circulated to the Bills Committee on 18 July 2007 vide LC Paper No. CB(1)2156/06-07(01).)

*Clause 2 – Commencement*

Admin 5. The Administration advised that it would make Committee Stage Amendments (CSAs) to amend the title of the "Secretary for Commerce, Industry and Technology" as stated in various proposed sections 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.

*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)*

6. The Bills Committee noted that the subsidiary legislation made under proposed section 72B(1) on the declaration of extreme urgency for public health problem would be subject to negative vetting by the Legislative Council (LegCo) and that it would come into operation on the day to be published in the Gazette. In this connection, members requested the Assistant Legal Adviser 2 to provide for reference an analysis on the consequential effect of the subsidiary legislation made under the proposed section 72B(1) in the event that a resolution to revoke it was passed by the LegCo.

ALA2

(*Post-meeting note*: The information provided by ALA2 was circulated to the Bills Committee on 18 July 2007 vide LC Paper No. LS102/06-07.)

7. In view of members' concern on the adoption of the term "the Government" in the proposed section 72E(2) and the various proposed sections in the Bill, which might not give clarity as to which authority within the Government was vested with the concerned power, the Administration undertook to consider whether the term should be revised and replaced by a suitable post title, and to advise the Bills Committee of its decision.

Admin

(*Post-meeting note*: The Administration's response was circulated to the Bills Committee on 17 July 2007 vide LC Paper No. CB(1)2142/06-07(01).)

8. The Administration advised in response to Mr WONG Ting-kwong's enquiry that the remaining stock of patented pharmaceutical products held by parties in the supply chain would likely be surrendered to the proprietor of the patent concerned if the extreme urgency leading to the issue of the import compulsory licence was over; or else the licence holder would be liable to civil litigation by the concerned patent holder if that person continued to put on the market or use the products. Mr WONG Ting-kwong requested the Administration to consider revising the relevant sections in the Bill to reflect the proper disposal of the remaining stock of patented pharmaceutical products held by parties in the supply chain if an extreme urgency was over or if the licence was due to expire. The Administration undertook to provide a written response.

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(*Post-meeting note*: The Administration's response was circulated to the Bills Committee on 17 July 2007 vide LC Paper No. CB(1)2142/06-07(01).)

9. With respect to the proposed section 72H(2), which stipulated that "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", the Chairman sought clarification as to whether sanctions would be imposed on violation of this subsection. The Administration replied that there were no sanctions imposed under this subsection. However, any person who, without a valid licence issued by the Department of Health, exported or caused to export the product out of Hong Kong would be liable to criminal sanctions under the Import & Export Ordinance (Cap. 60).

Arrangements for the next meeting

10. The Chairman reminded members that the next meeting would be held on 20 July 2007, at 2:30pm. He said that another meeting would be scheduled probably in September 2007 to continue the scrutiny of the Bill.

(*Post-meeting note*: At the advice of the Chairman, the next meeting has been rescheduled to 19 July 2007, at 10:45am.)

**III. Any other business**

11. There being no other business, the meeting ended at 4:30 pm.

Council Business Division 1
Legislative Council Secretariat
18 July 2007

**Appendix**

**Proceedings of third meeting of**
**Bills Committee on**
**Patents (Amendment) Bill 2007**
**on Thursday, 21 June 2007, at 2:30 pm**
**in Conference Room A of the Legislative Council Building**

| Time marker | Speaker | Subject(s) | Action required |
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| 000000 – 000149 | Chairman | Confirmation of minutes of the meeting held on 22 May 2007 (LC Paper No. CB(1)1894/06-07) | |
| 000150 – 000327 | Chairman | Opening remarks | |
| 000328 – 000833 | The Hong Kong Association of the Pharmaceutical Industry (HKAPI) | Presentation of views | |
| 000834 – 001509 | Democratic Party (DP) | Presentation of views | |
| 001510 – 002549 | Chairman<br>Administration | The Administration's briefing on its written response to DP's views tabled at the meeting (subsequently issued vide LC Paper No. CB(1)1998/06-07 on 26 June 2007)<br><br>The Administration advised in response to HKAPI's views that –<br><br>(a) on import of pharmaceutical products which must satisfy the criteria of bio-equivalence and bio-availability to ensure that the generic products as imported would not be of a lesser quality, the Administration took note of HKAPI's views. The Administration added that the proposals in the Bill would not conflict with the existing registration mechanism of pharmaceutical products in Hong Kong. | |

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| | | (b) the Administration also took note of HKAPI's views that the distribution of the pharmaceutical products so imported should be centralized. In this respect, the Administration assured that suitable arrangements would be made on the distribution of the imported pharmaceutical products taking into account the prevailing situation and the circumstances of extreme urgency.<br><br>(c) on the concern about the stocking of pharmaceutical products, the Administration stressed that in situation of extreme urgency, the local public health organization would assume a co-ordinating role to ensure that the public would have sufficient drugs to address the concerned public health problem. Moreover, in granting an import compulsory licence to any person, the Director of Health (DH) might impose any other terms or conditions as he thought fit under the proposed section 72D(1)(c), having regard to the public health needs in Hong Kong in the period of extreme urgency, including measures that would help prevent stocking and price speculation by parties involved in the supply chain.<br><br>(d) the introduction of the proposed compulsory licensing system was to ensure that parties in the supply chain would not violate the law of patent protection. | |

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| 002540 – 005519 | Chairman<br>HKAPI<br>Administration<br>Ms Margaret NG | Discussion on whether a general guideline would be introduced for observance by parties involved in the supply chain for the selling or stocking of the pharmaceutical products when the public health crisis was over.<br><br>The Administration's response –<br><br>In considering the issue of import/export compulsory licence, the DH would exercise his professional judgment and take into account the circumstances involved in deciding the valid licence period to be stipulated on the licence, as well as the terms and conditions to be imposed upon the licensee. Since the circumstances might vary from case to case, it might not be possible, if not impracticable, to issue a standard guideline which could be applicable to all the situations involved. In case any party was aggrieved by the decision of the DH in relation to the grant of a compulsory licence to import or export a pharmaceutical product or the terms or conditions of the import or export compulsory licence, he might apply to the court for review under the proposed sections 72I or 72Q in the Bill.<br><br>In response to the Chairman's enquiry as to whether the application for review of the DH's decision by the court was tantamount to suing the Government, the Administration explained that it was in fact a review of the decision made by the DH, and the court would also take into consideration the circumstances involved when deciding how to award the legal cost.<br><br>Discussion of the definition of "apply to the court for a review", the circumstances under which the proposed | The Administration to follow up as stated in paragraphs 3 and 4 of the minutes |

| Time marker | Speaker | Subject(s) | Action required |
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| | | sections 72I and 72Q would apply, and the decisions to be made by the court. | |
| 005520 – 005950 | Chairman<br>Administration | Clause 1 – Short title<br><br>Members raised no query<br><br>Clause 2 – Commencement<br><br>The Administration's advice that the Bill, if passed, would come into operation after the Protocol was ratified by two thirds of the World Trade Organization (WTO) Members, and the Administration would keep in view the developments in this respect.<br><br>Clause 3 – Interpretation<br><br>The Administration's advice that as the list of WTO Members recognized by the United Nations (UN) as being least-developed countries had already been promulgated by the UN, a schedule would not be added to the Bill listing out the concerned eligible importing members.<br><br>Clause 4 – Special provision regarding invention covered by 2 or more patents<br><br>Members raised no query | The Administration to follow up as stated in paragraph 5 of the minutes |
| 005951 – 015806 | Chairman<br>Administration<br>Assistant Legal Adviser 2 (ALA2)<br>Mr WONG Ting-kwong<br>Ms Margaret NG | 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)<br><br>Discussion of the operation of the proposed section 72B(2) on the declaration of extreme urgency for public health problem<br><br>The Administration explained in | The Administration /the Assistant Legal Adviser 2 to follow up as stated in paragraphs 6 to 8 of the minutes |

| Time marker | Speaker | Subject(s) | Action required |
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| | | response to members' enquiries that -<br><br>(a) A fee would not be imposed for the grant of import and export compulsory licences;<br><br>(b) the subsidiary legislation made under the proposed section 72B(1) was subject to negative vetting by the Legislative Council (LegCo); and<br><br>(c) on the proposed section 72D(2) which stipulated that "an import compulsory licence is non-exclusive", the Administration explained that an import compulsory licence might be granted to more than one person in accordance with the proposed section 72D(2).<br><br>Discussion of possible scenarios in which the proposed section 72D(1)(b)(iii) might or might not apply.<br><br>The Administration explained in response to Mr WONG Ting-kwong's enquiry that in line with the Protocol, the import compulsory licence was non-assignable, except with that part of the enterprise or goodwill established over time (such as reputation, turnover and performance of the enterprise, etc) which enjoyed the use of the patent under the licence as stipulated in the proposed section 72D(1)(b)(iii). The provision would not apply if the enterprise was only a shell company. Moreover, in considering whether or not an import compulsory licence should be issued, the DH would take into account whether the prospective licensee was a reputable, reliable and genuine importer, and thus a shell company would unlikely | |

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| | | be entitled to the grant of the licence.<br><br>Discussion of the reference of "the Government" as stated in the proposed section 72E(2). Ms Margaret NG pointed out that the phrase "establishes to the satisfaction of the Government" in the proposed section 72E was seldom used in other ordinances as it appeared inappropriate, if not unreasonable, to require the proprietor of the patent concerned to convince the Government, which could refer to the Chief Executive, the DH, etc, that the requisite remuneration had not been paid.<br><br>The Chairman's enquiry on the rationale for the DH to take into account the advice given by the Director of Intellectual Property (DIP) before reaching any agreement on the amount of remuneration to be payable under circumstances as stated in proposed section 72E(1) to (3).<br><br>The Administration's advice that -<br><br>(a) 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 DIP, | |

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| | | who had the expert knowledge in this respect with regard to the international scenarios and standards, and hence could provide the valuation of the patent for reference by the DH.<br><br>(b) while the DH, who was the licensing authority, would have the expertise to assess the value of the concerned pharmaceutical product in terms of its safety and efficacy, DIP could give advice to the DH, on the basis of third party expert or specialist advice where appropriate, on whether the pharmaceutical product concerned was patented in its territory, the rate prescribed for calculating the amount of remuneration with respect to the international standards, as well as other relevant factors relating to the grant of the licence, to facilitate the DH's negotiation with the proprietor of the patent concerned on the remuneration to be paid.<br><br>Mr WONG Ting-kwong considered the arrangement under the proposed section 72E(3) acceptable.<br><br>The Administration explained in response to the enquiries raised by the Chairman and Mr WONG Ting-kwong that -<br><br>(a) during consultation, one deputation had expressed the view that the 4% maximum cap on remuneration should be removed;<br><br>(b) when considering the amount of remuneration to be paid by the licensee, the Administration had drawn reference from other | |

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| | | jurisdictions (e.g. the European Union (EU)) which had indicated acceptance of the Protocol and were making/had made legislation to prescribe a maximum rate for calculating such amount. For most of the circumstances, the amount generally did not exceed a level equivalent to 4% of the total price to be paid by the importer for the product. The remuneration prescribed/proposed by such jurisdictions was usually determined on the grounds of the humanitarian and non-commercial considerations for the grant of licence which was to help the least-developed countries to address public health problems;<br><br>(c) according to the importing member's rank on the UN Human Development Index, the lower the ranking of the importing member on the Index, the lower the rate it would attract which could be less than 0.1%, whilst the maximum would be 4%;<br><br>(d) the Administration proposed to pitch the cap at 4% for the amount of remuneration and would continue to keep in view the international developments and re-visit the propriety of the 4% maximum cap if necessary; and<br><br>(e) the Secretary for Commerce, Industry and Technology would be delegated the authority to amend the cap by means of subsidiary legislation if considered necessary.<br><br>Mr WONG Ting-kwong queried about the rationale of pitching the cap at a high | |

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| | | level, i.e. 4%, and considered that the level of the maximum cap should be kept as low as possible for the benefit of Hong Kong.<br><br>The Administration's advice that:<br><br>(a) the proposals in the Bill had already struck a balance between the importance of patent protection and the need to facilitate access to pharmaceutical products for addressing public health problems;<br><br>(b) a certain number of WTO Members had chosen to pitch the maximum cap at 4%, which was also adopted by EU (comprising 27 member countries), for calculating the amount of remuneration; and<br><br>(c) although the pharmaceutical industry had expressed some concern towards the maximum cap to be pitched at 4% at the initial stage of consultation, it nevertheless did not raise fundamental objection.<br><br>In this connection, the Assistant Legal Adviser 2 (ALA2) advised that under the proposed section 72I(4) on references of disputes as to import compulsory licences, 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 was more than one patent in relation to the patented pharmaceutical product) might exceed the maximum amount of remuneration (i.e. 4%) which might be agreed under proposed section 72E(2)(a).<br><br>In relation to the proposed section 72F, the Administration explained in | |

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| | | response to the Chairman's enquiries that:<br><br>(a) the interpretation of "official journal" (OJ) had been stipulated in the existing section 2 of the Patents Ordinance (PO). OJ was an electronic notification posted on the online search system provided by the Intellectual Property Department (IPD);<br><br>(b) the term "Director" as stipulated in the proposed section 72F(1) referred to "the Director of Health" as provided under the proposed section 72A. In this connection, ALA2 advised that the Director of Intellectual Property was referred to as "Registrar of Patents" instead of "Director" under the PO; and<br><br>(c) there would be an administrative arrangement between the Department of Health and IPD, whereby the DH, as the licensing authority, would as soon as practicable after the grant of an import compulsory licence under section 72C notify IPD, so that the latter would advertise in OJ the notice of the grant of the licence and the relevant terms and conditions. As patent holders and practitioners often check information published in OJ to get hold of the information about patent applications and granted patents, it was considered appropriate to publish the information concerning the compulsory import licence on the OJ.<br><br>Discussion of possible scenarios in which the proposed section 72G might | |

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| | | and might not apply. The Administration stressed in particular that the DH would not come up with a decision lightly as to terminate the import compulsory licence, and he would only terminate the licence if there was serious violation of the terms and conditions imposed on the licensee. Under such circumstances, the person whose compulsory import licence had been terminated could no longer put on market, stock or use those imported pharmaceutical products; or else, his act would amount to an infringement of the patent concerned and attract civil liability. As to whether the DH would require the patent holder to surrender the pharmaceutical products so imported, it would depend on the circumstances involved including the terms and conditions of the licence and the arrangement made in the sourcing of the products. | |
| 015807 – 015828 | Chairman | Arrangements for the next meeting | |

Council Business Division 1
Legislative Council Secretariat
18 July 2007