

立法會
Legislative Council

LC Paper No. CB(1)154/07-08

Ref : CB1/BC/2/06

Paper for the House Committee meeting on 2 November 2007

Report of the Bills Committee on Patents (Amendment) Bill 2007

Purpose

This paper reports on the deliberations of the Bills Committee on Patents (Amendment) Bill 2007.

Background

2. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO) 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 needs to obtain prior authorization from the patent holder, or else, he will render himself liable to civil action.

3. Under Article 31 of the TRIPS Agreement, however, a WTO Member may allow a third party to use the subject matter of a patent (such as generic versions of patented drugs) without the authorization of the right holder, subject to certain obligations stipulated in the Article. Amongst these are the obligations that the patent holder has to be paid adequate remuneration (Article 31(h)), and that the use shall be predominantly for the supply of the domestic market of the WTO Member authorizing such use, which means that the majority of the product should not be exported (Article 31(f)). WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector may therefore face difficulties in making effective use of the compulsory licensing system as they cannot appeal to other economies with manufacturing capacity to export generic versions of the product to them. As such, the General Council of the WTO decided in August 2003 to temporarily waive the two obligations in Article 31(f) and (h) and to allow pharmaceutical products made under compulsory licences in one WTO Member to be exported to another WTO Member lacking production capacity.

4. In December 2005, the General Council of the WTO further adopted a Protocol Amending the TRIPS Agreement, which will replace permanently the temporary waiver if it is accepted by two thirds of WTO Members by 1 December 2007 (or such later date as may be decided by the Ministerial Conference of the WTO). The Protocol is meant for helping developing and least-developed economies to gain access to medicines. As such, while some WTO Members (mainly the developed economies) have indicated that they will not use the system under the Protocol to import medicine, some other WTO Members including Hong Kong have indicated that they will only use the system as an importer in situations of national emergency or circumstances of extreme urgency. As Hong Kong intends to notify the WTO of its acceptance of the Protocol, the existing Patents Ordinance (PO) (Cap. 514), which provides for a compulsory licensing framework modelled on Article 31 of the TRIPS Agreement, has to be amended before Hong Kong can implement and make use of the Protocol.

The Bill

5. The Bill seeks to amend the PO to implement the Protocol Amending the TRIPS Agreement in relation to patents and public health and to provide for incidental and related matters.

The Bills Committee

6. At the House Committee meeting on 20 April 2007, Members agreed to form a Bills Committee to study the Bill. Under the chairmanship of Hon SIN Chung-kai, the Bills Committee has held five meetings, including a meeting with deputations. The membership list of the Bills Committee is at **Appendix I**. A list of organizations that have submitted views to the Bills Committee is at **Appendix II**.

Deliberations of the Bills Committee

7. The Bills Committee supports in general the policy intent of the Bill and considers it appropriate to amend the PO thereby allowing Hong Kong to discharge its role as a responsible Member of the WTO in concert with the international community. While there is a possibility that by 1 December 2007 the Protocol may not have been accepted by two thirds of the WTO Members, members note that the deadline for acceptance is likely to be extended by the Ministerial Conference of the WTO. Under such circumstances, during the interim period between the acceptance of the Protocol by Hong Kong and the coming into effect of the Protocol, Hong Kong can 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. In the course of examining the Bill, members have raised concern on issues including the express reference to the decision of the General Council of the WTO, declaration of

extreme urgency, granting of import/export compulsory licences, termination of licences, handling of disputes regarding import/export compulsory licence by the court, the 28-day period for seeking court review, remuneration to the patent proprietor, and disposal of the remaining stocks of imported pharmaceutical products, etc.

Express reference to the decision of the General Council of the WTO

8. Members note that as of 12 September 2007, while ten WTO members (or 6.6% of the membership) have notified the WTO of their acceptance of the Protocol, some WTO members, including the European Union (with 27 member states) and Canada, are yet to appear on the acceptance list and these members are among the possible trading partners of Hong Kong, from whom Hong Kong may import patented pharmaceutical products in situations of extreme urgency. As such, the Administration has re-assessed the implications of a scenario, namely by the time when Hong Kong invokes the system, the Protocol is yet to take effect in these trading partners. The Administration further reckons that until such time as the Protocol has been accepted by all WTO members (which may take some time to materialize), the possibility cannot be ruled out that a WTO member from whom Hong Kong wishes to import (or to whom Hong Kong wishes to export) patented pharmaceutical products may still be relying on the General Council's decision (i.e. the temporary waiver mentioned in paragraph 3 above) as the basis for exporting to Hong Kong (or importing from Hong Kong) the patented pharmaceutical products. Under such a scenario, it is uncertain as to whether reliance on the General Council's decision (to which the Bill does not make express reference) will cause complications. To remove any doubt as to whether Hong Kong may rely on the provisions in the Bill to import or export patented pharmaceutical products from or to these WTO Members, members agree to the Administration's proposal to add express reference of the General Council's decision to the relevant provisions of the Bill.

Declaration of extreme urgency

9. Members note that the Administration has proposed to add in the proposed section 72B a subsection stating that "the period of extreme urgency declared under subsection (1) continues to run until such a date as may be specified by the Chief Executive in Council by notice published in the Gazette terminating the period of extreme urgency". Members are of the view that the end date of the period of extreme urgency should be specified in the said notice so as to provide certainty to all relevant parties, in particular those who have a commercial interest in the industry concerned. The Administration points out, however, that since it is difficult to foresee when a health crisis will be over, the end date of the period of extreme urgency cannot therefore be specified beforehand. To ensure that the interests of the concerned parties will be duly protected on the one hand and to allow flexibility for the Administration on the other, members suggest that the proposed provision be revised to the effect that the period declared will be kept under regular review until an end date is specified by the Chief Executive in Council by notice published in the Gazette terminating the period of extreme urgency. Members consider that such an

arrangement will provide a mechanism and a legal basis for any party whose interests are affected by the declaration of extreme urgency to apply for a court's order if the Chief Executive in Council does not terminate the period of extreme urgency even after reviewing that it should be so. The Administration takes on board members' suggestion and undertakes to add a new subsection to the proposed section 72B to provide that the period of extreme urgency will be subject to regular review.

Granting of import/export compulsory licences

10. Under the Bill, 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. During such a period of extreme urgency, if the Director of Health (DH) considers that Hong Kong has insufficient or no manufacturing capacity to make a certain pharmaceutical product to contain the public health problem in question, Hong Kong may use the Protocol to import the product. The DH may grant an import compulsory licence to any person to import, use, put on market, or stock the pharmaceutical product, or do any other act which will otherwise amount to an infringement of the patent concerned, without the consent of the proprietor of the patent. On the other hand, if a WTO Member indicates that it intends to avail itself of the Protocol or the General Council's decision to source a certain pharmaceutical product, any local manufacturer may, subject to the issue of an export compulsory licence by the DH, make use of the Protocol or the General Council's decision to make and export the product to the concerned Importing Member.

11. 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, members raise concern on whether the person to whom a patented pharmaceutical product is disposed of in accordance with an import compulsory licence can change the packaging of the product for the purpose of sale without entailing any sanctions. According to the Administration, all patented pharmaceutical products have to be registered with the Pharmacy and Poisons Board before they can be sold in Hong Kong. As such, a change of the packaging of the products after registration will not be allowed, and the sale of such products is tantamount to the selling of unregistered products which is in breach of the law and will be liable to sanctions.

12. In this connection, members note that pursuant to the Protocol, the entire quantity of the pharmaceutical product so imported should not be used for export to other places. They are concerned whether there is express provision in the Bill which stipulates the restriction for exporting the generic medicines to other places, say the Mainland for use by family members residing there, if those places are also having the same public health problem. The Administration explains that under the proposed section 72D(1)(b)(i) of the Bill, it has already been proposed that the patented pharmaceutical product which is imported into Hong Kong under the import compulsory licence should not be exported out of Hong Kong. Moreover, under the

Import and Export Ordinance (Cap. 60), any person who exports pharmaceutical products out of Hong Kong without a valid export licence issued by the DH will be liable to criminal sanctions. It is also proposed in the Bill that any person to whom a patent pharmaceutical product is disposed of in accordance with an import compulsory licence should not export or cause to export the product out of Hong Kong. With respect to the Mainland, the Administration points out that as the Mainland has already promulgated relevant order for implementation of the Protocol, it can also avail itself of the Protocol to source the necessary pharmaceutical product in case of public health problems.

13. Concerning the granting of an export compulsory licence, members note that under the proposed section 72K, a local manufacturer has to provide various information to support his application to the DH for the grant of the said licence. Since timely processing of the application is critical (as the Importing Member may well be facing national emergency or other circumstances of extreme urgency demanding urgent sourcing of the concerned pharmaceutical product to address the crisis), members suggest that standard statutory forms should be provided to facilitate local manufacturers in making such applications. Taking note of members' concern, the Administration undertakes to prepare relevant guidance notes and appropriate application forms to facilitate local manufacturers in making applications for the export compulsory licences. The Administration will also take into consideration the practice of other WTO Members in devising the administrative measures for export compulsory licences. The Administration's target is to have the measures in place within three months after the passage of the Bill.

14. In this connection, members note that both import/export compulsory licences are non-assignable, except with that part of the enterprise or goodwill which enjoys the use of the patent under the licence. Members enquire whether the DH, when imposing terms and conditions with respect to the import/export compulsory licence, will take into consideration possible changes to shareholding in the course of time such that the licensee to which the compulsory licence has been issued may change and hence the licence holder is no longer the original one which has applied to and been issued with such licence by the DH. The Administration explains that change of shareholding is a commercial activity which will not be taken into account by the DH when determining the terms and conditions of the compulsory licence, and it will also not absolve the licence holder from his obligations to abide by the terms and conditions prescribed by the DH when issuing the compulsory licence. In addition, the Administration assures members that in considering whether or not a compulsory licence should be issued, the DH will take into account whether the prospective licensee is a reputable, reliable and genuine importer/exporter, and a shell company is unlikely to be entitled to the grant of the licence. The DH may also consider revoking the licence if the licensee is not fulfilling the terms and conditions so imposed.

Termination of licences

15. Members note that the proposed section 72P(1)(b) stipulates that the DH may terminate the export compulsory licence if any information, document, or documentary evidence specified in or accompanying the application is false, incorrect or incomplete. While agreeing that the DH should terminate the licence if the applicant provides false information in his application, members consider that flexibility should be exercised in those cases where the information provided by the applicant is just incorrect or incomplete as such situations can be rectified by providing supplementary information, etc. According to the Administration, the DH may (as opposed to "should") terminate the export compulsory licence if he is satisfied, inter alia, that any information, document or documentary evidence specified in or accompanying the application is false, incorrect or incomplete in any material particular. The Administration assures members that the DH may exercise discretion not to terminate the licence if considered appropriate, such as where supplementary information can be provided by the licensee to rectify mistakes so made. To allay members' concern, the Administration assures members that the DH will not come up with a decision to terminate a licence lightly.

Handling of disputes regarding import/export compulsory licence by the court

16. The proposed sections 72I and 72Q empower the court to handle disputes relating to import/export compulsory licence. Specifically, the court is empowered to, inter alia, determine the amount of remuneration payable to the proprietor of the concerned patents under the above proposed sections.

17. In examining these two provisions, members are concerned that the proposed provisions, as currently drafted, do not spell out in an exhaustive manner the factors to be taken into account 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. They stress that since the court is not an administrative tribunal and the mission of the court is to execute the law, the aforementioned factors and basis should be clearly spelt out in law to provide a legal basis for the court to make decisions in relation to the determination of the amount of remuneration.

18. According to the Administration, there are provisions in other ordinances which also empower the court to determine monetary payment in default of agreement between the parties concerned. Examples include (a) section 32(4) of the Employees' Compensation Ordinance (Cap. 282); (b) section 38(8) of the Registered Designs Ordinance (Cap. 522); and (c) section 9 of the Antiquities and Monuments Ordinance (Cap. 53). On whether the proposed sections 72I and 72Q should be expanded to provide more parameters for assisting the court in determining the amount of remuneration payable, the Administration explains that currently, sections 72I(3) and 72Q(3) each provide two non-exhaustive factors to be considered by the court, namely, (a) the economic value of the use of the pharmaceutical product to the Importing Member; and (b) the humanitarian or non-commercial factors underlying the

authorization of the compulsory licence. Factor (a) is derived from the Protocol. Inclusion of this factor in sections 72I(3) and 72Q(3) aims to ensure compliance with the Protocol. Factor (b), on the other hand, provides the court with extra guidance. Before including these two parameters into the Bill, the Administration has already made reference to the relevant legislation of some developed WTO economies. Individual countries simply provide that “adequate” or “reasonable” remuneration should be paid. The European Union and Canada have adopted both factors (a) and (b) as the basis for determining the amount of remuneration payable. As such, the Administration is of the view that the provisions in the proposed sections 72I(3) and 72Q(3) are worked out on the basis of the international best practice, and already provide reasonably clear parameters for parties to the proceedings in making submissions and adducing evidence to substantiate their claims in the court. The non-exhaustive nature of sections 72I(3) and 72Q(3) also allows the parties to make submissions and adduce evidence in relation to other factors that they feel should be taken into account by the court in determining the remuneration. The current construction of sections 72I(3) and 72Q(3) facilitates the determination of remuneration without restricting the submission of other relevant evidence, including, for example, the prevailing international practices and the norm regarding remuneration under compulsory licence.

19. While members do not object to the current construction of the proposed sections 72I and 72Q, they consider that it is not the best arrangement for the court to determine the amount of remuneration payable to the proprietor of the patent concerned. They are of the view that such disputes should preferably be handled by a tribunal so that any person aggrieved by the decision of the tribunal can apply to the court for a judicial review. At members' request, the Administration undertakes to take the "tribunal" approach into consideration when it re-visits the adequacy of the current provisions in the future, having regard to overseas experience in applying provisions in the Protocol.

20. In this connection, members note that the provisions of Orders in the Rules of the High Court (RHC) and the inherent jurisdiction of the High Court apply to the proceedings under the PO. As such, the procedures for applications under the proposed sections 72I and 72Q will be provided for in the RHC, and the Administration will submit its proposals for consideration by the High Court's Rules Committee. In this regard, members request the Administration to consult the Hong Kong Bar Association and the Law Society of Hong Kong on the procedures for proceedings under the proposed sections 72I and 72Q, such as whether it should be by way of application, summons or originating motions, etc, and who will be empowered to make rules under the proposed provisions, etc, before submitting proposals to the High Court's Rules Committee for consideration. According to the Administration, it has already submitted its relevant drafts amending Order 103 of the RHC to the High Court's Rules Committee for consideration. The proposed new Order 103 seeks to lay down the procedures for the conduct of litigation and for making applications and references to the High Court on matters relating to provisions under the PO. In the light of the Rules Committee's comments, the Administration is now refining the drafts and will consider whether and if so how the proposed Order should be further

refined to provide for, inter alia, the procedures for the proceedings under the proposed sections 72I and 72Q. In this regard, the Administration takes on board members' suggestion to consult the legal and intellectual property practitioners, including the Hong Kong Bar Association and the Law Society of Hong Kong, subject to the Rules Committee's in-principle endorsement of the proposed amendments. The Administration also advises that the Order to be enacted is subsidiary legislation, i.e. subject to negative vetting by the Legislative Council.

The 28-day period for seeking court review

21. Under the proposed sections 72I(6)(d) and 72Q(1)(c), any person aggrieved by the termination of import/export compulsory licences may, within 28 days after 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. Since the person aggrieved by the DH's decision to terminate the licence may not be the licensee himself, and hence has to learn about such decision via the advertisement published in the official journal, which is only published as soon as practicable, but not immediately, by the DH, the aggrieved person may in fact have less than 28 days for applying to the court for a review. On the principle of equity and fairness, members consider that the date of the advertisement of the notice of termination should instead be used as the starting point for calculating the 28-day period.

22. According to the Administration, any person aggrieved by the termination of an import/export compulsory licence, may, within 28 days after the date of the termination of the licence, apply to the court for a review of such termination. To address members' concern and to ensure that a third party, other than the licensee, aggrieved by the termination can take note of it as soon as possible and hence has sufficient time for filing an application for a court review, the Administration agrees to make special arrangement such that the termination notice will be advertised in the official journal as soon as practicable (i.e. usually within the same day) and in any case not later than 24 hours from the DH's termination of the relevant licence. The Administration undertakes to ensure that the notice will be published in a timely manner, so as to tie in with the policy intent that sufficient time will be given to aggrieved parties for lodging of review. In this connection, the Administration advises that it has also assessed the merits of members' suggestion of using the date of advertising the termination notice as the starting point for calculating the 28-day period. However, the Administration points out that if the date of the advertisement of the notice is to be adopted, the licensee will not be able to apply to the court for a review until the relevant notice has been published in the official journal. However short such an interim period may be, issues such as the status of the patented pharmaceutical products held by the licensee and how such products should be dealt with during the interim period may arise. Hence, the Administration considers that the current starting point, i.e. the date of the termination of the licence, should be maintained.

23. In this connection, the Administration points out that the review made by the court under the Bill is in the form that may lead to variation of the DH's decision on,

say, termination of the licence, as opposed to "re-considering" the case afresh. Thus, the proposed sections 72I and 72Q will not affect the existing avenue for judicial review outside the Bill and the PO.

Remuneration to the proprietor of the patent

24. Under the Protocol, where an export compulsory licence is granted by an Exporting Member, adequate remuneration shall be paid to the proprietor of the patent in that Member. In line with the requirements under the Protocol, it is proposed in the Bill that the holder of an export compulsory licence granted in Hong Kong should pay remuneration to the local proprietor of the patent. The Administration further proposes that the amount of remuneration should be determined on a case-by-case basis by the DH on the advice of the Director of Intellectual Property (DIP), and it will not exceed a level equivalent to 4% of the total price to be paid by the importer for the product. If adequate remuneration is paid at the exporting end, no remuneration is required to be paid at the importing end. However, an obligation to pay remuneration to the proprietor of the patent at the importing end will 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, such as where the manufacturer at the Exporting Member's end goes bankrupt and cannot pay the remuneration.

25. Members enquire about the rationale of pitching the cap at 4%, and consider that the level of the maximum cap should be kept as low as possible for the benefit of Hong Kong. The Administration explains that, in drawing up the 4% cap, it has taken into account the mechanisms adopted by other WTO Members, namely the European Union, Canada and Switzerland. They have prescribed (or are about to prescribe) a maximum rate or a formula for calculating the amount of remuneration (and, in both cases, the amount generally does not exceed a level equivalent to 4% of the total price to be paid by the importer for the product). The Administration stresses that such a proposal (i.e. pitching the cap at 4%) has already struck a balance between the importance of patent protection and the need to facilitate access to pharmaceutical products for addressing public health problems. Moreover, although the pharmaceutical industry has expressed some concern towards the maximum cap to be pitched at 4% at the initial stage of consultation, it does not raise fundamental objection.

26. The Administration points out further that in case Hong Kong imports a pharmaceutical product under the Protocol, it does not need to pay any remuneration to the patent proprietor unless adequate remuneration is not paid at the exporting end after all legal remedies to recover such payment have been exhausted. Under such extremely rare circumstances, the Administration proposes 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. The amount of remuneration will be agreed between the proprietor of the patent and the DH on the advice of the DIP, and the cap will be equivalent to 4% of the total price paid by the Hong Kong

importer for the product. Nevertheless, in the light of members' concern, the Administration undertakes to review the propriety of the cap in the course of time, having regard to the prevailing international practice. In this regard, it is noted that the Secretary for Commerce and Economic Development may by way of notice in the Gazette vary the said percentage. The Administration adds that any dispute regarding the remuneration may be referred to the court.

27. Members enquire as to how a local proprietor can effectively prove to the DH that remuneration has not been paid at the Exporting Member's end. The Administration explains that the DH will assess the information tendered by the local proprietor, such as direct/indirect verbal or written information and circumstantial evidence. Moreover, with global patent ownership, local patent proprietor may request the Exporting Member's end to check with the patents registry concerned to verify and prove to the DH whether remuneration has been paid to the patent proprietor at the Exporting Member's end.

Disposal of the remaining stocks of imported pharmaceutical products

28. Members enquire about the status of the remaining stock of patented pharmaceutical products when the extreme urgency leading to the issue of the import compulsory licence is over. According to the Administration, an import compulsory licence will terminate when the extreme urgency leading to the declaration is over. As such, if any person puts on the market, stocks, or uses the remaining quantity of the patented pharmaceutical product imported after the expiry of the licence, he may infringe the patent concerned and entail civil liability. In this regard, members raise concern as to how the business interests of the traders importing and supplying the patented pharmaceutical product can be safeguarded when the extreme urgency leading to the declaration is over and there is remaining stock of the product.

29. According to the Administration, in sourcing and importing generic medicines from other places, the Government will probably need to rely on pharmaceutical companies in the private sector. When using the system under the Bill to import a patented pharmaceutical product, Hong Kong should be facing a situation of extreme urgency resulting from a public health problem or threatened public health problem. A possible scenario is that the Government will use public money to procure the patented pharmaceutical product. The import compulsory licence holders and other traders along the supply chain will act as agents of the Government in sourcing and distributing the product. The Government will coordinate the distribution of the product to the end-users in the community for the protection of public health. The remaining stock is therefore owned by the Government, but not the licence holders or individual traders.

30. However, as the import compulsory licensing system is intended to address a wide range of emergency situations, the mode of procurement and distribution of the required patented pharmaceutical product may evolve depending on the circumstances of the case. Hence, the Administration points out that it is also possible that the procurement funded by the Government is not adequate to contain the crisis in

question. As such, private sector initiative may have to be sought to procure and source the required patented pharmaceutical product. Under this scenario, import licence holders and other traders down the supply chain may be concerned that they cannot sell the remaining stock after the expiry of the licence. To address such concerns and in response to members' request, the Administration undertakes to introduce specific provisions 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. Alternatively, a licence holder may choose to negotiate with the patent owner on his own, and keep or dispose of the stock if agreed by the patent owner. Depending on the circumstances of the case, the Government may reach a mutual understanding with the prospective licence holder concerning the arrangement prior to the issue of the import compulsory licence. In this connection, the Administration will also add a provision to specify that during the period of negotiation with the patent proprietor, the stocking of the imported pharmaceutical products should not be regarded as patent infringing. Moreover, end-users possessing the product for personal consumption will not entail infringement.

31. In this connection, members enquire whether a general guideline will 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 is over. The Administration explains that since the circumstances may vary from case to case, it may not be possible to issue a standard guideline which will be exhaustive and applicable to all the situations involved. In case any party is aggrieved by the decision of the DH in relation to the issue of an import compulsory licence, he may apply to the court for a review.

Committee Stage amendments

32. A full set of the draft Committee Stage amendments to be moved by the Administration is in **Appendix III**.

Recommendation

33. The Bills Committee supports the Administration's proposal that the Second Reading debate on the Bill be resumed on 21 November 2007.

Advice sought

34. Members are invited to support the recommendation of the Bills Committee in paragraph 33 above.

Bills Committee on Patents (Amendment) Bill 2007

Membership List

Chairman	Hon SIN Chung-kai, SBS, JP
Members	Hon Margaret NG Hon LI Kwok-ying, MH, JP Hon WONG Ting-kwong, BBS (Total : 4 members)
Clerk	Miss Erin TSANG
Legal Adviser	Mr Timothy TSO
Date	4 May 2007

Bills Committee on Patents (Amendment) Bill 2007

**List of organizations which have made
written and/or oral representations to the Bills Committee**

1. Médecins Sans Frontieres Hong Kong
2. Democratic Party
3. Hong Kong Bar Association
4. Hong Kong Association of the Pharmaceutical Industry
5. The Law Society of Hong Kong

PATENTS (AMENDMENT) BILL 2007

COMMITTEE STAGE

Amendments to be moved by the Secretary for
Commerce and Economic Development

<u>Clause</u>	<u>Amendment Proposed</u>
2	By deleting "Secretary for Commerce, Industry and Technology" and substituting "Secretary for Commerce and Economic Development".
3	(a) In the proposed definition of "eligible importing member", in paragraph (b), by deleting "Article 31 bis in" and substituting "the General Council Decision or". (b) In the proposed definition of "exporting member", by deleting "Article 31 bis in" and substituting "the General Council Decision or". (c) In the proposed definition of "Protocol", by adding ", the Annex to the Protocol Amending the TRIPS Agreement, the Annex to the TRIPS Agreement and the Appendix to the Annex to the TRIPS Agreement" after "2005". (d) By adding - "Doha Declaration" (多哈宣言) means the Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001

by the Fourth WTO Ministerial Conference
at Doha, Qatar;

"General Council Decision" (《總理事會決定》)

means the Decision adopted by the General
Council of the WTO on 30 August 2003 on
the Implementation of Paragraph 6 of the
Doha Declaration;

"relevant instrument or legislation" (有關文書或
法例) means -

- (a) the General Council Decision;
- (b) the Protocol; or
- (c) legislation made by the
exporting member or the
eligible importing member, as
the case may be, pursuant to or
for the purpose of implementing
-
 - (i) the General Council
Decision; or
 - (ii) the Protocol;".

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(a) By deleting the proposed section 72B(2) and
substituting -

"(2) Where a period of extreme urgency
has been declared under subsection (1), the
Chief Executive in Council shall review from
time to time, or cause to be reviewed from
time to time, the public health problem or the
threatened public health problem leading to

the declaration.

(3) The period of extreme urgency declared under subsection (1) continues to run until such a date as may be specified by the Chief Executive in Council by notice published in the Gazette terminating the period of extreme urgency.

(4) A notice published under subsection (1) or (3) is subsidiary legislation."

- (b) In the proposed section 72E(1), by deleting "Article 31 bis in the Protocol and Article 31(h) of the TRIPS Agreement" and substituting "the relevant instrument or legislation".
- (c) In the proposed section 72E(2) -
 - (i) by deleting "to the satisfaction of the Government" and substituting "to the satisfaction of the Director";
 - (ii) by deleting "Article 31 bis in the Protocol and Article 31(h) of the TRIPS Agreement" and substituting "the relevant instrument or legislation".
- (d) In the proposed section 72E(6), by deleting "Secretary for Commerce, Industry and Technology" and substituting "Secretary for Commerce and Economic Development".
- (e) By deleting the proposed section 72F(2) and substituting -
 - "(2) The Director shall -
 - (a) as soon as practicable after

any amount of remuneration has been agreed under section 72E(2)(a) between him and the proprietor of the patent concerned, advertise in the official journal a notice stating -

- (i) the amount of remuneration so agreed with the proprietor of the patent concerned named in the notice and, where applicable, the apportionment of the amount of remuneration under section 72E(5); and
 - (ii) that any other person who is entitled to claim remuneration payable under section 72E(2) may make an application to the court under section 72I(2); or
- (b) as soon as practicable after he is satisfied that he and the proprietor of the patent concerned have failed to agree on the amount of remuneration payable under section 72E(2),

advertise in the official journal a notice stating -

- (i) the fact of the failure to agree on the amount of remuneration with the proprietor of the patent concerned named in the notice; and
- (ii) that any other person who is entitled to claim remuneration payable under that section may make an application to the court under section 72I(2).".

(f) By adding -

"72GA. Disposal of patented pharmaceutical products after period of extreme urgency etc.

(1) On the termination of the period of extreme urgency by a notice under section 72B(3), the import compulsory licensee shall take reasonable steps to recall or cause to recall any patented pharmaceutical product which is imported under the import compulsory licence from any person (other than a person who is in possession of the product privately for non-commercial purposes) who is in possession of the product disposed of in accordance with the licence.

(2) An import compulsory licensee shall -

- (a) surrender to the Director any patented pharmaceutical product which is in his possession or recalled under subsection (1); or
- (b) dispose of the product in such a way as may be agreed with the proprietor of the patent concerned granted in Hong Kong.

(3) Where a patented pharmaceutical product is surrendered to the Director under subsection (2)(a) -

- (a) the Government shall pay to the import compulsory licensee a sum equivalent to the purchase price for the product paid by the licensee to the seller of the product in the exporting member; and
- (b) the Director shall -
 - (i) dispose of the product in such a way as may be agreed with the proprietor of the patent concerned granted in Hong Kong; or
 - (ii) in default of agreement,

destroy the product as
soon as practicable.

(4) For the avoidance of doubt, stocking of any patented pharmaceutical product which is imported under an import compulsory licence does not amount to an infringement of the patent concerned on the part of the import compulsory licensee or the Director from the termination of the period of extreme urgency by a notice under section 72B(3) until -

(a) the import compulsory licensee surrenders the product to the Director under subsection (2)(a) or disposes of the product under subsection (2)(b); or

(b) the Director disposes of the product under subsection (3)(b)(i) or destroys the product under subsection (3)(b)(ii),

as the case may be."

(g) In the proposed section 72K(2)(b) -

(i) in subparagraph (ii)(C), by deleting "Article 31 bis in the Protocol and Article 31 of the TRIPS Agreement" and substituting "the relevant instrument or legislation";

(ii) in subparagraph (iii), by adding "where

applicable," before "a copy".

- (h) In the proposed section 72M(1)(b)(iii), by deleting "dedicated to and maintained for the purpose of Article 31 bis in the Protocol".
- (i) In the proposed section 72O(4), by deleting "Secretary for Commerce, Industry and Technology" and substituting "Secretary for Commerce and Economic Development".