Bills Committee on the Patents (Amendment) Bill 2007

Issues raised at the Bills Committee meeting on 21 June 2007

Introduction

At the Bills Committee meeting on 21 June 2007, Members asked the Administration to clarify –

(a) which party within the Government should the local patent proprietor approach when the latter seeks to establish, under the proposed section 72E(2), that remuneration had not been paid to the patent proprietor at the exporting end;

(b) how the proposed sections 72I and 72Q introduced by the Patents (Amendment) Bill 2007 ("the Bill") are intended to operate;

(c) how the remaining stock of patented pharmaceutical product imported under an import compulsory licence would be disposed of when the extreme urgency leading to the declaration under the proposed section 72B(1) was over or when the import compulsory licence was due to expire.

2. This paper provides the information as requested.

The proposed section 72E(2)

3. As the Director of Health (DH) is the licensing authority for import and export compulsory licences under the Bill, we consider it appropriate for the local patent proprietor to come forward to DH to prove that remuneration had not been paid to the patent proprietor at the exporting end after the exhaustion of all legal remedies there. The relevant departments within the Government would provide advice and assistance to DH in assessing the information tendered by the local proprietor. Should the fact be established to the DH's satisfaction, DH would negotiate with the local patent holder regarding the amount of remuneration to be paid under the proposed section 72E(2). We will move Committee Stage Amendments (CSAs) to amend section 72E(2) so that "Government" where it first appears will be replaced with "the Director". As it would be for the Government to pay the remuneration, it is not necessary to change the reference to "Government" where it subsequently appears in the provision.

The proposed sections 72I and 72Q

Judicial review or not?

4. The proposed section 72I empowers the Court of First Instance ("the court") to handle disputes as to import compulsory licences. Specifically, the court is empowered to –

(a) determine the amount of remuneration payable to the proprietor of the patent concerned in default of agreement between the Director of Health (DH) and the proprietor of the patent concerned;

(b) determine any claim for remuneration made by the proprietor of the patent concerned who is not a party to any agreement reached on the amount of remuneration under the proposed section 72E(2)(a);

(c) ***review*** the grant of an import compulsory licence, its terms and conditions, the apportionment of remuneration and termination of an import compulsory licence, by the DH;

(d) terminate an import compulsory licence if any term or condition of the licence has been contravened; and

(e) make any other order as it thinks fit in the circumstances under the proposed section 72I(7)(e) & (9)(b).

5. The proposed section 72Q empowers the court to handle disputes as to export compulsory licences. Specifically, the court is empowered to –

(a) ***review*** the grant of an export compulsory licence, its terms or conditions, and termination of an export compulsory licence, by the DH;

(b) ***review*** the determination of the amount of remuneration payable to the proprietor of the patent concerned;

(c) terminate an export compulsory licence if any term or condition of the licence has been contravened or any information, document or documentary evidence specified in or accompanying the application in accordance with section 72K(2) is false, incorrect or incomplete in any material particular; and

(d) make any other order as it thinks fit in the circumstances under the proposed section 72Q(2)(e) & (6)(b).

6. It is not our intention for the term "review" in the proposed sections 72I and 72Q to be taken as judicial review. The court is empowered to review DH's decision relating to the concerned matters (please see paragraphs 4(c) and 5(a) and (b) above). In a review, the court may (a) confirm, vary or cancel the licence in question or any term or condition contained therein; (b) confirm or reverse the termination of the licence; (c) confirm or vary the apportionment/determination of the amount of remuneration; or (d) make any other order as it thinks fit in the circumstances (the proposed sections 72I(7) and 72Q(2) refer). The review should be in the form that may lead to "variation" of DH's decision, as opposed to "re-considering" the case afresh.

7. The proposed sections 72I and 72Q would not affect the existing avenue for judicial review. In such proceedings, the court is empowered to examine the reasonableness, fairness and procedural propriety of an administrative/statutory decision. Section 21K of the High Court Ordinance (Cap.4) and Order 53 of the Rules of the High Court (RHC) (Cap. 4, sub. leg. A) apply to the proceedings of judicial review.

Determining the amount of remuneration

8. The proposed section 72I(1) empowers the court to determine the amount of remuneration payable in default of agreement between DH and the patent proprietor for cases of import compulsory licences. This is modelled on the existing section 71(5) of the Patents Ordinance (Cap 514) which governs government use[1] of patented inventions. We have not found any case law in relation to the existing "government use" provisions. Hence, we could not point to any reference from case law as to what the court would take into account in such cases.

9. We believe that the parties to the proceedings would adduce evidence to substantiate their claim in the court. Whether additional evidence is required for the purpose of determining the amount of remuneration would depend on the circumstances of individual case. There are provisions in other Ordinances which 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).

---

[1] The existing Government use provisions (sections 68 to 72) in the Patents Ordinance give to the Government the right to use a patented invention without the need for any prior licence from the patent proprietor in periods of extreme urgency under specified conditions. The provisions apply to all type of inventions and are in line with Article 31 of WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Unlike the Protocol which the Bill seeks to implement, the government use provisions are subject to the condition that the use shall be *predominantly* for the supply of the domestic market of the WTO Member authorising such use (i.e., the majority of the product should not be exported).

Rules of procedures

10. At present, the provisions of Orders in the RHC and the inherent jurisdiction of the High Court apply to the proceedings under the Patents Ordinance. The relevant Orders include Order 5 which governs the mode of commencing civil proceedings; Order 25 which stipulates the procedures for seeking court directions; Order 55 which deals with appeals; and Order 62 which handles costs. The procedures for applications under the proposed sections 72 I and 72Q will be provided in the RHC. The Administration will submit its proposals for the High Court Rules Committee's consideration in due course.

Disposal of the remaining stock of patented pharmaceutical product

11. An import compulsory licence would terminate when the extreme urgency leading to the declaration under the proposed section 72B(1) is over. If any person puts on the market, stocks, or uses the remaining quantity of the patented pharmaceutical product imported (as defined under the Bill) after the expiry of the licence, he may infringe the patent concerned and entail civil liability. Prior consent of the patent proprietor needs to be sought before the remaining quantity could be kept in stock for future use. The import compulsory licence holders should be required to arrange recall of the products along the supply chain at their own expense. This arrangement is in line with the existing mechanism under which pharmaceutical products need to be recalled on drug safety grounds. End-users holding the product for personal consumption would not amount to infringement and hence would not be affected.

12. At the last Bills Committee meeting, there was 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 the proposed section 72B(1) was over and there was remaining stock of the product. In sourcing and importing generic medicines from other places, the Government would 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 would use public money to procure the patented pharmaceutical product. The import compulsory licence holders and other traders along the supply chain would act as agents of the Government in sourcing and distributing the product. The Government would coordinate the distribution of the product to the end-users in the community for the protection of public health. The remaining stock is owned by the Government, but not the licence holders or individual traders.

13. That said, 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 would evolve depending on the circumstances of the case. Hence, 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 should be sought to procure and source the required patented pharmaceutical product. Under this scenario, import licence holders and other traders down the supply chain would be concerned as they could not sell the remaining stock after the expiry of the licence. This may affect the private sector's incentive to assist the Government to source the required product to address a crisis. We are 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. Alternatively, a licence holder may choose to negotiate with the patent owner on his own and keep the stock. 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.

14. For the protection of public health, it may be worthwhile to stockpile the remaining quantity of patented pharmaceutical product in case Hong Kong faces a similar emergency in the future. The Government would liaise with the patent proprietor concerned regarding the disposal of the remaining stock if it intends to keep the stock for future use. During the period of negotiation with the patent proprietor, the stocking and any act involved in the recall that may infringe the patent concerned should not be regarded as patent infringing. If the patent proprietor refuses to give consent to the keeping of the remaining stock for future use, the remaining quantity would need to be destroyed.

15. As regards the scenario whereby the extreme urgency was not over and the import compulsory licence was due to expire, the Director of Health may, prior to the expiry of the licence, exercise the power conferred upon him under s.46 of the Interpretation and General Clauses Ordinance (Cap.1) to renew the licence.

Commerce, Industry and Tourism Branch
Commerce and Economic Development Bureau
July 2007