Bills Committee on the Patents (Amendment) Bill 2007

Issues raised at
the Bills Committee meeting on 19 July 2007

Introduction

At the Bills Committee meeting on 19 July 2007, Members asked the Administration to –

(a) consider whether more parameters could be added to sections 72I(3) and 72Q(3) to facilitate the court's determination of the amount of remuneration payable;

(b) report on the progress of preparing legislative amendments to the Rules of High Court for the application of the proposed sections 72I and 72Q;

(c) re-assess the appropriateness of using "the date of the termination of the licence" for the application for court review in sections 72I(6)(d) and 72Q(1)(c); and

(d) explore feasible administrative arrangements to facilitate local manufacturers in applying for export compulsory licences for patented pharmaceutical products under section 72K.

2. This paper provides the information as requested.

Proposed sections 72I and 72Q - determining the amount of remuneration

3. Members asked whether sections 72I(3) and 72Q(3) could be expanded to provide more parameters for the court in determining the amount of remuneration payable.

4. Currently, sections 72I(3) and 72Q(3) each provide two non-exhaustive factors to be considered by the court, namely, (a) the economic value to the eligible importing member; and (b) the humanitarian or non-commercial factors. Factor (a) was derived from the second paragraph of Article 31*bis*, Annex to the Protocol Amending the TRIPS Agreement ("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 Patents (Amendment) Bill 2007 ("the Bill"), we had made reference to the relevant legislation of some developed countries. 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.

5. We believe the provisions in the proposed sections 72I(3) and 72Q(3) 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) means that the parties could also 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.

6. The temporary waiver (which precedes the Protocol) adopted by the General Council of the World Trade Organization (WTO) in August 2003 has rarely been used[1] in the international arena, let alone being tested in court. In the circumstances, the Administration considers it appropriate to proceed on the basis of the current provisions in the Bill (which are in alignment with the best practices known to us). We will re-visit the adequacy of the current provisions in the course of time, having regard to overseas experience in applying provisions in the Protocol.

High Court Procedures for applications under proposed sections 72I and 72Q

7. The Administration has submitted its relevant drafts amending Order 103 of the Rules of High Court (Cap. 4 sub. leg. A) to the High Court 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 Patents Ordinance (Cap. 514). Under the proposed Order, there are rules which provide for the commencement of proceedings by way of originating summons,

[1] Since the inception of the temporary waiver system in August 2003, only one notification had so far been made. In July 2007, Rwanda notified the WTO of its intention to import HIV/AIDS medicine (TriAvir) produced in Canada, pursuant to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

the requirements and the service of an originating process. There are also rules governing the procedures for appointing a scientific adviser and for serving documents on a proprietor of a patent.

8. 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, amongst others, the procedures for the proceedings under the proposed sections 72I and 72Q. Subject to the Rules Committee's in-principle endorsement of the proposed amendments, the Administration will consult the legal and intellectual property practitioners, including the Hong Kong Bar Association and the Law Society of Hong Kong. The Order (to be enacted) is subsidiary legislation, subject to negative vetting by the Legislative Council.

Reference point for calculating the 28-day period for the application for court review in sections 72I(6)(d) and 72Q(1)(c)

9. Members were worried that a third party, other than the import/export compulsory licensee, aggrieved by the termination of an import/export compulsory licence might have relatively less time for making application to the court for a review under the proposed sections 72I(6)(d) and 72Q(1)(c), having regard to the possibility that the notice announcing such termination might not be posted immediately.

10. Under sections 72I(6)(d) and 72Q(1)(c), 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. At the same time, sections 72G(2) and 72P(2) require the Director of Health (DoH) to advertise in the official journal notice of the termination as soon as practicable. To ensure that a third party, other than the licensee, aggrieved by the termination could take note of it as soon as possible and hence have sufficient time for filing an application for a court review, we have decided to make special arrangement such that the termination notice under sections 72G(2)(b) or 72P(2)(b) (as the case may be) will be advertised in the official journal as soon as practicable and in any case within one day from DoH's termination of the relevant licence. DoH will work closely with the Intellectual Property Department (who is responsible for the posting of the notice in the official journal) to ensure that the notice will be published in a timely manner.

11. We have also assessed the merits of using the date of advertising the termination notice as the starting point for calculating the 28-day period. The

current sections 72I(6) and 72Q(1) enable any person who feels aggrieved by DoH's decision to terminate the licence to immediately file an application with the court, and the court may then make an order under sections 72I(7)(e) or 72Q(2)(e), as the case may be, regarding the patented pharmaceutical products pending the court's determination of the review application. If the date of the advertisement of the notice under section 72G(2)(b) and 72P(2)(b) were to be adopted, the licensee would not be able to apply to the court under sections 72I(6)(d) or 72Q(1)(c) 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, we consider that the current starting point, i.e. the date of the termination of the licence, should be maintained. At the same time, we would endeavour, as pledged in paragraph 10, to ensure that aggrieved parties other than the licensee, if any, would be given sufficient time to file an application for a court review.

Administrative arrangements to facilitate application for export compulsory licences

12. Members asked whether administrative arrangements would be made to facilitate local manufacturers in applying for export compulsory licences for patented pharmaceutical products under section 72K.

13. The Administration would prepare relevant guidance notes and appropriate application forms to facilitate local manufacturers in making applications for the export compulsory licences. We would take into consideration the practice of other WTO members in devising the administrative measures for export compulsory licences. Our target is to have the measures in place within three months after the passage of the Bill.

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