

立法會 *Legislative Council*

LC Paper No. LS53/06-07

Paper for the House Committee Meeting on 20 April 2007

Legal Service Division Report on Patents (Amendment) Bill 2007

I. SUMMARY

1. **Objects of the Bill** To amend the Patents Ordinance (Cap. 514) to implement the Protocol Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”) of the World Trade Organisation (“WTO”) in relation to patents and public health and to provide for incidental and related matters.
2. **Comments**
 - (a) On 6 December 2005, the General Council of the WTO adopted the Protocol which effectively waives the obligations set out in Article 31(f) and Article 31(h) of the TRIPS Agreement in specified circumstances. The decision allows pharmaceutical products made under compulsory licences in one WTO Member to be exported, without the restriction of Article 31(f), to another WTO Member lacking production capacity.
 - (b) The existing Patents Ordinance (Cap. 514) (“the Ordinance”) would have to be amended before Hong Kong could make use of the Protocol.
 - (c) The main provisions in the Bill are described in paragraph 21 of the LegCo Brief and the Explanatory Memorandum of the Bill. The proposed clause 5 of the Bill adds two new parts to the Ordinance. The proposed Part IXA governs the grant of import compulsory licences for patented pharmaceutical products, and the proposed Part IXB governs the grant of export compulsory licences for patented pharmaceutical products.
3. **Public Consultation** The relevant stakeholders were consulted on the proposed amendments in late 2006. The respondents in general gave in-principle support to the proposal.
4. **Consultation with LegCo Panel** The Panel on Commerce and Industry was briefed on the legislative proposals contained in the Bill at its meeting on 19 December 2006. The Panel was in principle supportive of the Administration’s proposal.
5. **Conclusion** The Legal Service Division is still scrutinizing the legal and drafting aspects of the Bill. Members may wish to consider setting up a Bills Committee to scrutinize the details of the proposed amendments as suggested by the Panel on Commerce and Industry.

II. REPORT

Objects of the Bill

To amend the Patents Ordinance (Cap. 514) to implement the Protocol Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organisation in relation to patents and public health and to provide for incidental and related matters.

LegCo Brief Reference

2. The LegCo Brief (File Ref: CIB CR 06/08/11) issued by the Commerce, Industry and Technology Bureau dated 28 March 2007.

Date of First Reading

3. 18 April 2007.

Comments

4. 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. By virtue of Article 31(f) of the TRIPS Agreement, the majority of the product made under a compulsory licence should be predominantly for the supply of the domestic market, not being for export. It has been noted that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of the existing compulsory licensing system.

5. In August 2003, the General Council of the WTO decided to temporarily waive the obligations set out in Article 31(f) and Article 31(h) of the TRIPS Agreement in specified circumstances. In effect, the decision allows pharmaceutical products made under compulsory licences in one WTO Member to be exported, without the restriction of Article 31(f), to another WTO Member lacking production capacity. On 6 December 2005, the General Council of the WTO further adopted the Protocol which would replace the temporary waiver and give permanent effect to the arrangements.

6. The Protocol is open for acceptance by WTO Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference of the WTO. The Protocol will take effect upon acceptance by two thirds of the WTO Members.

7. According to paragraph 8 of the LegCo Brief, Hong Kong has declared that it would not use the system as an importer unless in situations of national emergency or other circumstances of extreme urgency. The existing Patents Ordinance (Cap. 514) (“the Ordinance”) would have to be amended before Hong Kong could make use of the Protocol.

8. The main provisions in the Bill are described in paragraph 21 of the LegCo Brief and the Explanatory Memorandum of the Bill.

9. Clause 5 of the Bill proposes to add two new parts to the Ordinance. The proposed Part IXA relates to the grant of import compulsory licences for patented pharmaceutical products and the proposed Part IXB relates to the grant of export compulsory licences for patented pharmaceutical products. Some of the provisions in these two Parts are highlighted below.

10. In the proposed Part IXA, the proposed section 72B empowers the Chief Executive in Council to declare a period of extreme urgency for the purposes of applying provisions in relation to import compulsory licences in order to address any public health problem or threatened public health problem in Hong Kong. The proposed section 72C empowers the Director of Health (“the Director”) to grant an import compulsory licence, under certain circumstances, to a public officer or other person to import, put on the market, stock or use a patented pharmaceutical product or to do any other act in Hong Kong in relation to the product which would, but for the import compulsory licence, amount to an infringement of the patent concerned. The proposed section 72D provides for the terms and conditions to be imposed on import compulsory licences and the nature of the licences. The proposed section 72E provides for the payment of remuneration to the proprietor of the patent concerned.

11. In the proposed Part IXB, the proposed section 72K provides for the application for an export compulsory licence and the requirements to be met. The proposed section 72L empowers the Director to grant an export compulsory licence, under certain circumstances, to make and sell a patented pharmaceutical product for export to an eligible importing member. The proposed section 72M provides for the terms and conditions to be imposed on export compulsory licences and the nature of the licences. The proposed section 72O provides for the payment of remuneration to the proprietor of the patent concerned.

Public Consultation

12. According to paragraph 25 of the LegCo Brief, the relevant stakeholders, including the major medical, legal and intellectual property practitioners’ associations, the major trade associations representing the pharmaceutical industry, local universities, as well as non-governmental organisations, were consulted on the proposed amendments in late 2006. The respondents in general gave in-principle support to the proposal. Nevertheless, some respondents had argued for removal of the cap on the remuneration payable to the local proprietor of the patent.

Consultation with LegCo Panel

13. The Panel on Commerce and Industry was briefed on the legislative proposals contained in the Bill at its meeting on 19 December 2006. The Panel was in

principle supportive of the Administration's proposal and the Administration was urged to introduce the Bill as soon as possible for the Legislative Council's deliberation.

Conclusion

14. The Legal Service Division is still scrutinizing the legal and drafting aspects of the Bill. Members may wish to consider setting up a Bills Committee to scrutinize the details of the proposed amendments as suggested by the Panel on Commerce and Industry.

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