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Bills Committee on Patents (Amendment) Bill 2007

Background brief

Purpose

This paper gives a summary of discussion by the Panel on Commerce and Industry (the Panel) regarding the proposal to amend the Patents Ordinance (PO) (Cap. 514) in order to implement a Protocol adopted by the General Council of the World Trade Organization (WTO) in December 2005 which aims to facilitate access to generic versions of patented drugs for addressing public health problems.

Introduction

2. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the 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 would need 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 issue a compulsory licence allowing a third party to use the subject matter of a patent (such as generic versions of patented drugs) provided that the patent holder has to be paid adequate remuneration, and 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. WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector can 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 obligations as set out in the above Article 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 the Protocol as mentioned in paragraph 1, which would replace permanently the temporary waiver if it was accepted by two thirds of WTO Members by 1 December 2007 (or such later date as might be decided by the Ministerial Conference of the WTO). Hong Kong, as a WTO Member, intends to notify the WTO of its acceptance of the Protocol. In this connection, the existing PO, which provides for a compulsory licensing framework modelled on Article 31 of the TRIPS Agreement, has to be amended to implement the Protocol.

The Bill

5. The main objective of the Bill is to amend the PO to implement the Protocol.

Issues raised by the Panel

6. On 19 December 2006, the Panel received a briefing on the aforesaid proposal by the Administration. The Panel noted that as proposed by the Administration, the Chief Executive-in-Council might declare a period of extreme urgency in Hong Kong by way of notice in the Gazette if it was considered necessary or expedient in the public interest to do so to address any public health problem or threatened public health problem. During such a period of extreme urgency, if the Director of Health (the Director) was satisfied that Hong Kong had insufficient or no manufacturing capacity to manufacture a certain pharmaceutical product to address the public health problem in question, the Director might grant a compulsory licence to any person to import, use, and distribute etc, the pharmaceutical product without the consent of the patent holder. Likewise, as an Exporting Member, Hong Kong might also make use of the system under the Protocol to export generic versions of patented pharmaceutical products if a WTO Member indicated that it intended to avail itself of the Protocol to source a certain pharmaceutical product. It was proposed that the Director be empowered to issue such compulsory licences.

7. The Panel was, in principle, supportive of the Administration's proposal to amend PO for fulfillment of the international obligation to implement the Protocol. The Panel also considered that the implementation of the Protocol would be particularly useful in face of public health problems such as avian influenza. Nevertheless, members had expressed concern on the amount of remuneration to be paid to the patent holder. The Administration explained that 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, in extreme circumstances (such as where the manufacturer at the Exporting Member’s end went bankrupt and could not pay the remuneration), the Director might have to determine the amount of remuneration to be paid to the local patent holder by, say, making reference to the international practices then prevailing. The patent holder,

if aggrieved at the decision made by the Director, could appeal to the Court of First Instance for adjudication.

8. In the case of Hong Kong being the Exporting Member, the Administration explained that according to the Protocol, there was an obligation on the part of the Exporting Member to pay adequate remuneration to the patent holder, taking into account of the economic value of the use of the drugs to the Importing Member. In this regard, reference was drawn from other jurisdictions which had indicated acceptance of the Protocol, or had made/were making legislation or measures to implement the Protocol such as the Mainland China, the European Union, Canada and Switzerland. To allow for greater flexibility in determining the amount of remuneration payable to the patent holder, the Administration proposed that there would not be a formula prescribed in the PO. Instead, the amount of remuneration would be determined on a case-by-case basis but it would not exceed 4% of the total price to be paid by the Importing Member for the product on the grounds of the humanitarian and non-commercial considerations underlying the promulgation of the Protocol which was to help needy WTO Members with public health problems. Nevertheless, the Administration had undertaken to continue to keep international developments in view and might re-visit the propriety of pitching the cap at 4%. Similarly, any dispute regarding the amount of remuneration might be referred to the Court of First Instance.

Relevant papers

9. A list of relevant papers and the minutes of the Panel meeting on 19 December 2006 previously issued are available on the Legislative Council website at http://www.legco.gov.hk/yr06-07/english/bc/bc02/general/bc02.htm and http://www.legco.gov.hk/yr06-07/english/panels/ci/minutes/ci061219.pdf.

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