**The Administration's response to submissions made by Medecins Sans Frontieres and the Democratic Party to the Bills Committee on the Patents (Amendment) Bill 2007**

| Item | Observations | The Administration's response |
|---|---|---|
| **1. Submissions from Medecins Sans Frontieres** | | |
| 1.1 | Support the proposal to empower the Director of Health (DH) to decide when to import a generic version of a patented medicine under a compulsory licence, after the Chief Executive has declared a period of extreme urgency. | Noted. |
| 1.2 | Support the proposal of limiting the period of prior negotiations, if required, between the patent proprietor and the generic medicine manufacturer to 28 days in order to avoid undue delay. | Noted. |
| 1.3 | Support the proposal of fixing a cap at 4% for the remuneration payable to avoid abuses in case of exports under a compulsory licence. | Noted. |
| 1.4 | Suggest providing a simplified and accelerated procedure for the export compulsory licence holder to alter the quantity of medicine to be manufactured and exported under the licence. | If the importing Member of the World Trade Organization ("WTO") is facing an extreme urgency, our proposed mechanism in the Patents (Amendment) Bill 2007 ("the Bill") has already provided for a simplified procedure for obtaining an export compulsory licence (e.g. prior negotiation with the patent proprietor for a voluntary licence is not required). We believe that where a larger quantity of a medicine is required for export, the process of issuing a fresh compulsory licence would not be unduly complicated or lengthy. If the importing WTO Member is not facing an extreme urgency, we consider it not appropriate to adopt a fast-track procedure, having regard to the needs for safeguarding the interests of the patent proprietor. |

| Item | Observations | The Administration's response |
|---|---|---|
| **2. Submissions from the Democratic Party** | | |
| 2.1 | The Bill introduces Clause 72B, which stipulates that "the Chief Executive in Council may by notice publish in the Gazette declare a period of extreme urgency whenever the Chief Executive in Council considers it to be necessary or expedient in the public interest to do so to address any public health problem or threatened public health problem in Hong Kong". However, what circumstances would be regarded as conditions warranting declaration of extreme urgency or threatened public health problem? When discussing the Bill, the Committee may wish to have in-depth discussion with the Administration as to what conditions would constitute urgent situations. | (i) If there is a public health crisis that may have profound impact on human lives or protection of public health, a situation of extreme urgency under the Patents Ordinance (Cap. 514) would arise. This would call for the application of s. 72C – 72I.<br><br>(ii) The Doha Declaration states, among other things, that "Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstance of extreme urgency." We envisage that a pandemic would be one of the situations where the Administration would consider declaring a period of extreme urgency. |
| 2.2 | Thailand's recent issue of "compulsory licences" for certain medicines has led to a series of disputes. If other poorer countries issue compulsory licences for similar reasons (i.e. for addressing persistent public health problems like AIDS rather than urgent situations like wars and infectious diseases) in future, would the Department of Health issue export compulsory licences as a matter of course? | (i) The amendments set out in the Bill are proposed mainly for the purpose of implementing a Protocol which is open to acceptance by WTO Members. By amending the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") of the WTO, the Protocol facilitates Members' access to generic versions of patented pharmaceutical products when addressing public health problems. It is envisaged that beneficiaries may include some developing and least-developed countries which are afflicted with serious public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. Some WTO Members[1] have indicated that they would not make use of the |

[1] These WTO Members include Australia, Canada, the European Union and its member states, Iceland, Japan, New Zealand, Norway, Switzerland and the U.S.

| Item | Observations | The Administration's response |
|---|---|---|
| | | system under the Protocol as importers, while 11 Members[2], including Hong Kong, have declared that they would not take advantage of the system as importers unless in situations of national emergency or other circumstances of extreme urgency. As for the remaining WTO Members, they may use the system for importing pharmaceutical products regardless of whether or not they are in situations of national emergency or other circumstances of extreme urgency. Upon enactment and commencement of the Bill, if certain WTO Members wish to import generic versions of patented pharmaceutical products under the framework of the Protocol for addressing public health problems and a Hong Kong manufacturer intends to make the products for export to those countries, the latter may apply for an export compulsory licence under the Patents Ordinance. The DH will decide whether the compulsory licence should be issued under the system as set out in the Bill.<br><br>(ii) Under the proposed section 72K in the Bill, if a WTO Member intends to import a patented pharmaceutical product referred to in the Bill according to the mechanism under the Protocol when it is not faced with a national emergency, an applicant for an export compulsory licence in Hong Kong should, before applying for such a licence, make reasonable efforts to obtain authorisation from the proprietor of the patent concerned on reasonable commercial terms and conditions to make and sell for export the patented pharmaceutical product. The DH would consider granting the export compulsory licence only if the applicant has failed to obtain the authorisation within 28 days. However, for cases where the WTO Member which intends to import a patented pharmaceutical |

[2] These 11 WTO Members are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates.

| Item | Observations | The Administration's response |
|---|---|---|
| | | product has declared that it is under national emergency or other circumstances of extreme urgency, the foregoing requirements would not apply. This is consistent with the requirements under the Protocol. As a WTO Member, Hong Kong has to comply with the requirements in implementing the Protocol.<br><br>(iii) As regards the Democratic Party's reference to the Thai Government's recent issue of "compulsory licences" for three medicines, we understand that the medicines involved were manufactured in Thailand for local consumption. Hence, it does not relate to the import and export of medicines as envisaged under the Protocol. |
| 2.3 | When the proprietor of the patent at the exporting end is unable to recover the payment of the remuneration, the HKSAR Government, instead of the holder of the import compulsory licence, would pay the remuneration to the proprietor of the patent in Hong Kong. The HKSAR Government would use public funding for paying remuneration to the proprietor of the patent for importing the medicine to address the needs in Hong Kong. Given government subsidies and the lower cost of the medicine compared with patented medicine, importers and retailers would be able to make substantial profit. As such, the Government should consider imposing terms and conditions in the import compulsory licences to prevent stocking and price speculation by importers and retailers, a situation that would put public health at risk. | (i) Hong Kong has indicated that it would not use the system under the Protocol to import generic versions of patented medicines as an importer unless in situations of national emergency or other circumstances of extreme urgency. Where Hong Kong imports a pharmaceutical product under the Protocol, an obligation to pay remuneration to the proprietor of the patent in Hong Kong will arise only 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. We expect that such circumstances will be extremely rare. Where such a situation arises, we consider it appropriate for the HKSAR Government to 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.<br><br>(ii) The Bill provides a mechanism for preventing abuses of the import compulsory licensing system. Under section 72C, the DH may grant an import compulsory licence to importers whom he considers |

| Item | Observations | The Administration's response |
|---|---|---|
| | | reputable and reliable. Besides, in granting an import compulsory licence to any person, the DH may impose any other terms or conditions as he thinks fit under section 72D(1)(c), having regard to the public health needs in Hong Kong in the period of extreme urgency, including measures that help prevent stocking and price speculation by parties involved in the supply chain. |
| 2.4 | For the export of pharmaceutical products, adequate remuneration shall be paid to the patent proprietor at the exporting end. It is believed that many countries with no manufacturing capacities in the pharmaceutical sector are poor and less developed countries. The amount of remuneration payable by them to the proprietor of the patent at the importing end may be lower. In addition, the remuneration payable to the patent proprietor by the Exporting Member would be determined having regard to the economic value of the use of the medicines to the Importing WTO Member. It is believed that there would be difficulties for a place to assess the economic value of the use of a non-patented medicine to another place. Also, there may be a number of importing WTO members afflicted with the same disease. This may further complicate the assessment of remuneration payable to the patent proprietor. It should be more practicable to pay at the importing end the remuneration to the patent proprietor. | The arrangement of paying remuneration to the patent proprietor at the exporting end as proposed in the Bill is made in accordance with the requirements under the Protocol. As a WTO Member, Hong Kong has to observe the requirements when implementing the Protocol. |