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Council for Trade-Related Aspects of Intellectual Property Rights

TRANSITIONAL REVIEW MECHANISM OF CHINA

Communication from the United States

Addendum

By means of a communication from the delegation of the United States, dated 25 October 2005, the Secretariat has received the following supplemental questions to China in the context of the transitional review mechanism under Section 18 of China's Protocol on Accession. It was circulated as an advance copy for the Council's October 2005 meeting.

PATENTS AND UNDISCLOSED INFORMATION

1. China's patent office has adopted an "early warning system" to advise local companies of possible patent infringement in product development. With respect to this system, please clarify:

- (a) whether foreign companies, including foreign invested enterprises (FIEs) established in China, may participate in this "early warning system;"
- (b) the scope of this "early warning system;" and
- (c) whether the Chinese government renders any advice regarding avoiding or minimizing infringement as part of this early warning system.

2. Are there any efforts underway to provide substantive examination for design patents?

3. Has China granted any patents for business methods? If so, how many? How many enforcement actions have involved such business method patents since their issuance?

4. During last year's TRM, China explained that the State Food and Drug Administration (SFDA) was conducting an investigation into the linkage between patent approval and drug approval processes (*see* WTO IP/C/M/46, para. 25). Please report on the results of this investigation, and whether a written report is available.

5. The United States has heard reports that China's State Intellectual Property Office (SIPO) has been investigating the provision of patent term restoration for pharmaceutical products that lose part of their patent life due to delays in regulatory approval. Please describe the nature of these efforts. What is their current status?

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6. Please provide the most current information available (from July 2004 to the present) on (a) the number of domestic and foreign patent applications filed, (b) the types of patent filings involved (invention/design/utility model); and (c) the length of time from the filing of each application until determination, broken down according to specific technical fields.