

I. Bolar Exception

In order to balance the interest of patent holders for drugs and medical apparatus and instruments and the public interest with a view to improving the availability of generic drugs, China amended its *Patent Law* in 2008 and introduced Item (5) under Article 69, which provided any person who produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or any other person who produces and imports patented drugs or patented medical apparatus and instruments especially for that person, shall not be deemed to infringe patent right. That provision has the same legislative intention and regulatory content as the "Bolar Exception" as requested by WIPO. "Administrative examination and approval" mentioned therein shall be understood as covering the administrative examination and approval conducted by both Chinese and foreign drug administrations, and those acts permitted in that provision can be conducted at any stage of the term of protection of the relevant patent. That provision has been implemented smoothly for nearly a decade and no obvious problems have ever been caused so far.

II. Provisions in the *Guidelines for Patent Examination* that are relevant to the topics listed in Paragraph 8 of Document SCP/24/3

Paragraph 8 of Document SCP/24/3 listed a number of topics concerning the assessment of inventive step, including common general knowledge, combination

inventions, avoidance of hindsight analysis, secondary factors, selection inventions, and the assessment of inventive step in the chemical sector. The relevant provisions appear at least in the following Chapters of the China *Guidelines for Patent Examination*:

Combination invention: 4.2 of Chapter 4, Part II;

Avoidance of hindsight analysis: 6.2 of Chapter 4, Part II;

Secondary factors: 5.1 to 5.4 of Chapter 4, Part II;

Selection inventions: 4.3 of Chapter 4, Part II; and

Assessment of inventive step in the chemical sector: 6.1 to 6.2 of Chapter 10, Part II.