★Co-located Session

2015. 03. 18

[C8] Overseas Expansion of Pharmaceutical/Bio Industry and Strategic Response to Patent-Approval Linkage System

April 10(Fri), 09:00~12:00 / Room.318

We intend to introduce the ANDA litigation practice under the Patent-Approval Linkage System in the United States and the biosimilar approval practice under the BPCIA enacted in 2010, and consider the details of the Patent-Approval Linkage System to be implemented on March 15, 2015 in Korea and relevant legal issues and practical countermeasures therefor, and then introduce the case where a domestic company successfully entered the overseas market, and address legal issues that need to be taken into account in overseas expansion.

Session 1. Understanding of Approval and Patent System in the United States and Plan for Utilization 09:10~10:10

Speakers

09:10~09:40 **Approval of biosimilars in the United States**
Mann, Jeffry S., Attorney, Morgan Lewis & Bockius LLP

09:40~10:10 **ANDA litigation**
Rich de Bodo, Attorney, Morgan Lewis & Bockius LLP

10:10~10:20 Session Break

Session 2. Introduction of Korean Patent-Approval Linkage System and Practical Countermeasures 10:20~11:20

Speakers

10:20~10:50 **Understanding of Korean Patent-Approval Linkage System Implemented on March 15, 2015**
Hyun Jung Park, Official, Patent-Approval Linkage Division of Ministry, Food and Drug Safety

10:50~11:20 **Legal Issues Arising from the Implementation of Patent-Approval Linkage System and Practical Countermeasures**
Jung Hi Park, Attorney, Bae, Kim & Lee LLC

Session 3. Strategy for Overseas Expansion of Domestic Pharmaceutical/Bio Industry 11:20~12:00

Speakers

11:20~11:40 **Case of Successful Overseas Market Entry of Kanarb and Current Progress**
Sung Won Choi, Managing Director, Head of Global Business Division, Boryung Pharmaceutical

11:40~12:00 **Legal Considerations in Overseas Expansion of Domestic Company**
Won Hee Cho, Attorney, Bae, Kim & Lee LLC