The Korea-U.S. Free Trade Agreement (KORUS FTA), which took effect on March 15, 2012, introduced a marketing approval-patent linkage system to deter patent infringement prior to obtaining marketing approval for a generic drug, namely, where a generic applicant requests marketing approval for a generic drug based on the stability and efficacy data of the drug filed by an innovator to obtain generic marketing approval.

The marketing approval-patent linkage system based on the KORUS FTA is schematically set forth below.

A person or entity having obtained marketing approval for an original drug must file an application to list patent information relating to the approved drug, such as the patentee, patent term and scope of protection in the Patent List (“Green List”) of the Korea Food & Drug Administration (KFDA). (Step ① in the diagram)

A generic applicant is obligated to notify the patentee and the marketing approval holder for the drug listed in the Green List of the fact that an application for generic marketing approval was applied for with the KFDA. (Steps ② and ②’ in the diagram) The generic applicant must provide notification of the following items:

- Application Date of Marketing Approval for a generic drug;
- The fact that marketing approval for a generic drug was applied for with submission of bioequivalence test results based on the stability and efficacy data of the approved drug for the purpose of commercial manufacture, import or sales prior to the expiration of the patent of the approved drug; and
- Patent Certificate stating that the listed patent is invalid or the drug for which generic marketing approval was applied for does not infringe on the listed patent.

One is exempted from the notification obligation above in the following cases:

(i) Where the patent term of the listed patent has expired;
(ii) Where generic marketing approval is applied for under the condition that the drug would be sold after the listed patent has expired;
(iii) Where there is consent by the patentee, et al. or anything equivalent thereof; or
(iv) Where the Intellectual Property Tribunal or a court rendered, prior to filing the application for generic marketing approval, a decision that the listed patent is invalid or a decision that the drug for which generic marketing approval is applied for does not fall within the scope of the listed patent.

Suspension of approval for a generic drug, i.e., steps ③, ④ and ⑤ in the foregoing diagram, will be implemented after a three-year transition period, i.e., as of March 15, 2015. Under the fully implemented system, in the case where a patentee who has been notified of an application for generic marketing approval files a patent lawsuit, the approval will be suspended until the patent lawsuit is resolved. A suspension period of up to a maximum of 12 months is under consideration concurrently with a first generic exclusivity period of 180 days to provide generic applicants with an incentive to challenge invalid patents.

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