Healthcare

The National Assembly Passed the Amendment to the Pharmaceutical Affairs Act

On March 3, 2015, the National Assembly passed the Amendment to the Pharmaceutical Affairs Act (the "Amendment to the PAA") relating to the patent-approval linkage system. The Amendment to the PAA which was proposed by the Health and Welfare Committee integrates and adjusts the bill proposed by the government dated October 22, 2014 (the "October Bill") and the bill brought before the National Assembly on motions of several members of the National Assembly dated December 15, 2014 (the "December Bill"). The Amendment to the PAA will come into force on March 15, 2015.

(1) Stay of Generic Sales

With respect to the stay mechanism where the owner of the listed patent may apply for a stay of generic sales, the Amendment to the PAA reduces the stay period from 12 months from the date when the owner of the listed patent received a notice from the generic applicant (the "Date of the Receipt of the Notice") as proposed by the October Bill to 9 months from the Date of the Receipt of the Notice. The shortened stay period is expected to induce earlier market entry of generics and to expedite decisions in invalidation actions or declaratory judgment actions involving listed patents.

(2) First Generic Exclusivity

While the December Bill suggested that the first generic exclusivity should not be allowed as it could provide incentives for collusion between the owner of the listed patent and the generic applicant, the Amendment to the PAA introduces the exclusivity mechanism, but shortened the exclusivity period from 12 months from the date of the first generic approval as proposed by the October Bill to 9 months from the date when the generic for which the exclusivity is granted can be marketed.

To be eligible for the first generic exclusivity under the Amendment to the PAA, a generic applicant must be the first one filing an action challenging the listed patent (i.e. an action to invalidate the listed patent or the patent term extension, or a declaratory judgment action) or must subsequently file such an action within 14 days from the filing of the first action. On the other hand, the Amendment to the PAA also provides that a generic applicant who files an action challenging the listed patent must immediately notify the Ministry of Food and Drug Safety (the "MFDS") of its filing so that the MFDS may disclose information about the filed action on its webpage (Article 50-7 (3)). Under the eligibility requirements and the disclosure mechanism, multiple generic applicants may be granted the first generic exclusivity, which might make the first generic exclusivity less attractive to generic companies, contrary to the overall intent of the Amendment to the PAA.

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The Amendment to the PAA also provides that to be eligible for the first generic exclusivity, a generic applicant must obtain a favorable decision in an action challenging the listed patent within 9 months from the Date of the Receipt of the Notice. In the Legislation Review Sub-Committee meeting held on February 24, 2015, the Health and Welfare Committee opined that this requirement would not adversely affect a generic applicant's obtaining the 9 month exclusivity as the Korea Intellectual Property Office (the "KIPO") had announced that they would expedite processes of actions related to the patent-approval linkage system, and the average time required for an action to be decided by the KIPO was 7.9 months in 2014.

	October Bill	December Bill	The Amendment to the PAA Passed by the National Assembly
Stay Period	12 months from the Date of the Receipt of the Notice	12 months from the date of the notice	9 months from the Date of the Receipt of the Notice (Article 50-6 (1))
First Generic Exclusivity Period	12 months from the date of the first generic approval	The first generic exclusivity should not be allowed.	9 months from the date when the generic for which the first generic exclusivity is granted can be marketed (Article 50-9 (1))

Meanwhile, on June 20, 2014, the Ministry of Health and Welfare (the "MOHW") proposed the Partial Amendment to the National Health Insurance Act (the "Amendment to the NHIA") which provides that an original drug company may disgorge the amount of reimbursement unduly paid by the National Health Insurance Service as unjust profits gained by the original drug company, if it brought a patent dispute for purposes of delaying the market entry of generics and then lost the dispute. Notwithstanding the MOHW's request that the Amendment to the NHIA should be considered and enforced along with the Amendment to the PAA in order to stave off financial losses in the National Health Insurance system, the National Assembly deferred the consideration of the Amendment to the NHIA until the provisional session in April.

Yoon & Yang's Health Care Practice Group provides advice to pharmaceutical companies on a variety of issues concerning drug approvals and patent disputes including those relating to patent-approval linkage system. Please feel free to contact Yoon & Yang's Health Care Practice Group if you have any inquiries about the Amendment to the PAA.

JIYUL YOO
jyoo@yoonyang.com TEL. +82-2-6003-7552

YOUNG SUN CHO
ycho@yoonyang.com TEL. +82-2-6003-7518

YOON & YANG LLC
19th Fl., ASEM Tower, 517 Yeongdong-daero,
Gangnam-Gu, Seoul, Korea 135-798
Tel: +82-2-6003-7000 Fax: +82-2-6003-7800
Website; www.yoonyang.com; www.hwawoo.com