Introduction of the Patent-Market Approval Linkage System under the Amended Pharmaceutical Affairs Act

Under the patent-market approval linkage system, whether a patent of an original drug has been infringed is taken into account as a factor in granting a market approval for a generic drug. The patent-market approval linkage system was first developed in the U.S. and subsequently adopted by other countries including Canada and Australia. Pursuant to the Korea-U.S. Free Trade Agreement, Korea also agreed to introduce and implement the system from March 15, 2015. As the patent-market approval linkage system is related to the approval of drugs, the relevant provisions are set forth in the Pharmaceutical Affairs Act (the "Act"). There has been much discussion over how the Act should be amended to introduce the system, and the proposed amendments to the Act (the "Amended Act") were finally confirmed and passed at the Plenary Session of the National Assembly in March 3, 2015. The Amended Act is set to take effect on March 15, 2015. The following is the overview of the key aspects of the patent-market approval linkage system.

1. Introduction of Prohibition on Sale of Generic Drug

Under the Act prior to the amendments, if a generic drug company intends to release a generic drug with the same ingredients as those of the patented original drug by filing an application for market approval based on the safety and efficacy data of the patented original drug, in order to prohibit the sale of such generic drug in the market, the patent holder (i.e., the original drug company) had to file an action seeking a court order to prohibit an infringement of a patent or an application for a preliminary injunction, and obtain a favorable court decision. Under the current National Health Insurance system, it is important for original drug companies to prevent the release of generic drugs in advance in order to avoid a decrease in the maximum price of the original drugs, but as it generally takes considerable time for the court to come to a conclusion, it was practically impossible for original drug companies to prevent the release of generic drugs in advance. To solve such problem, the Amended Act provides for measures to prevent the sale of a generic drug that challenges the

patent of the original drug during the approval stage of the generic drug.

The generic drug sale prevention mechanism involves (i) original drug companies' listing of patents covering original drugs on the patent list and (ii) generic drug companies' notification to the listed patent owners and market approval holders of the filing of generic drug applications for market approval. The Ministry of Food and Drug Safety (the "MFDS") has the authority to prepare and maintain such list of patents covering original drugs, and the holders of the market approval for the original drugs (or approval on any amendment thereof) may list the patent(s) for the original drugs with the consent of the patent holders or the exclusive licensees thereof (collectively, the "Patent Holder"). The original drug patent to be listed must be (i) directed to a substance, formulation, composition, or medical use of the drug, (ii) directly related to the matters of the drug of which the approval (or amendment approval) was granted, and (iii) a patent which has been applied for before the date of market approval (or approval on change thereof) (Article 50-2 of the Amended Act). If the patent of an original drug is listed, an applicant for the market approval on generic drug (or amendment approval regarding the drug efficacy and effectiveness pursuant to Article 31(9) of the Act), who intends to sell the generic drug during the effective term of the listed patent, must notify certain facts relating to his application for market approval to the Patent Holder of the listed patent within 20 days after the application date ("Patent Challenge Notice"). The failure to send a Patent Challenge Notice would delay the generic approval application date. The notice requirement also applies to a generic drug company which initially decides not to challenge the listed patent of the original drug company but subsequently decides to challenge the patent and applies for the amended approval (Article 50-4 of the Amended Act).

The Patent Holder may request a stay against the sale of the generic drug to the Minister of the MFDS within 45 days after receiving the Patent Challenge Notice. As a prerequisite to the stay request, the Patent Holder must file a patent infringement action against the generic approval applicant challenging the list patent or initiate an action for confirmation of patent scope of the listed patent against the generic approval applicant or is otherwise subject to a patent scope confirmation trial initiated by the generic approval applicant. In addition, the Patent Holder must attach to the stay request a statement setting forth that: (i) the request is made for a duly registered patent, and (ii) the action against the generic approval applicant has been filed in good faith, which will likely result in an outcome favorable to the Patent Holder and will not unreasonably delay the proceeding (Article 50-5 of the Amended Act). When a request for a stay against generic drug sales is filed by the Patent Holder through the procedures above, unless the request is found to be unlawful or the listed patent has already been extinguished, the Minister of the MFDS must suspend the sale of the generic drug concerned for 9 months from the date of the Patent Challenge Notice at the time the MFSD grants the market approval of the generic drug (or an amendment approval). If the Patent Challenge Notice is made for two or more generic drugs with the same main ingredients, formulation, usage and amount, and efficacy and effectiveness, the Patent Holder must request a stay against the sale of all such generic drugs. If the MFDS has already granted market approval (or amendment approval) for any of such generic drugs,

the stay cannot be imposed on the other generic drugs even if such other generic drugs have not been approved (Article 50-6 of the Amended Act). On the other hand, no Patent Holder may request a stay against the sale of the same generic drug again unless an application for amendment approval relating to its efficacy or effectiveness has been made (Article 50-5(3) of the Amended Act).

The patent-market approval linkage system under the Amended Act is different from its U.S. counterpart in certain aspects. Under the U.S. system, the approval process per se for a generic drug becomes subject to automatic stay once the Patent Holder files a proceeding against the generic drug company challenging the patent. However, in Korea, while the approval process itself is not suspended, the sale of the generic drug may be delayed following the grant of market approval for the drug, and the stay against the generic drug sales is enforced only by a decision of the Minister of the MFDS, and not immediately upon the filing of a proceeding by the Patent Holder. In addition, the suspension period of the approval process is 30 months under the U.S. system, while the stay period under the Amended Act in Korea has been finally determined to be 9 months instead of 12 months as a result of the deliberation process for the proposed amendments to the Act, which is far shorter than the stay period under the U.S. system.

2. Introduction of First Generic Exclusivity System

By linking the patent right of the original drug company to the MFDS's market approval for the generic drug, the original drug company now has the means to immediately and effectively limit market competition with generic drugs. However, this also may lead to an increased likelihood of abuse of the patent right, such as restricting the sale of a generic drug based on an invalid patent for an original drug. As a legislative measure to avoid such unintended shortcomings and to encourage generic drug companies to challenge the listed patents, the Amended Act introduced the first generic exclusivity system, under which a generic drug company that is the first to successfully challenge a patent is granted exclusivity to distribute the generic drug concerned in the market for a certain period of time.

More specifically, a generic approval applicant that intends to send a Patent Challenge Notice may apply for the first generic exclusivity simultaneously at the time it applies for the market approval or amendment approval (Article 50-7 of the Amended Act). To be granted the first generic exclusivity which prohibits other generic drug companies from selling the same generic drug for 9 months from the date on which the generic drug is available for sale, the applicant must: (i) be the first to apply for market approval or amendment approval for the generic drug (if multiple applications are made on the same day, all of the applicants will have the same priority), (ii) have filed a trial seeking invalidation of the listed patent or scope confirmation trial prior to the date of the application for first generic exclusivity and obtained a favorable decision or judgment, and (iii) be the first to file such proceeding (or file such proceeding within 14 days after the first proceeding) or has already obtained a favorable court decision before the first proceeding (Article 50-8 and 50-9 of the Amended Act). The proceeding

under subparagraph (ii) includes any proceeding filed before the enforcement date of the Amended Act, but with respect to the timing of the filing of a proceeding under subparagraph (iii) above, all proceedings filed prior to the enforcement date of the Amended Act will be deemed to have been filed on the day immediately preceding the enforcement date (Article 3 of the Addendum of the Amended Act).

The first generic exclusivity recognizes the exclusive distribution right of generic drug companies, although it has not been adopted by all countries and the enforcement measures differ significantly from one country to another. For example, in the U.S. where the patent-market approval linkage system originated, the maximum period of first generic exclusivity is 180 days, which is shorter than the period granted under the Amended Act in Korea. On the other hand, Canada and Australia which have also introduced the patent-market approval linkage system decided not to adopt the first generic exclusivity mechanism. In Korea, whether to adopt the first generic exclusivity or not was heavily disputed until the proposed amendments to the Act and was finally passed with a compromise to reduce the exclusivity period from 12 months to 9 months.

3. Other Provisions of the Amended Act

The Amended Act also includes provisions that require the Minister of the MFDS (i) to analyze and evaluate potential effects of the patent-market approval linkage system on the domestic pharmaceutical industry, health care policies and employment rate, and publicly disclose and report to the National Assembly the results of such analysis (Article 50-11 of the Amended Act), and (ii) to collect data on market trends and prices of the listed patented drugs, provide assistance to small-and-medium-sized enterprises regarding the listing of patents, provide education and training for pharmaceutical companies on patents on drugs, analyze patent information of the listed drugs, and conduct research on overseas cases and policy studies (Article 50-12 of the Amended Act). Furthermore, as a measure to prevent any reverse payment agreement which was an issue raised during the implementation of the patent-market approval linkage system in the U.S., the Amended Act requires details of an agreement between the original drug company and generic drug company regarding the manufacture or distribution of a drug subject to a patent dispute or an agreement among generic drug companies regarding the first generic exclusivity be reported to the Minister of the MFDS and the Korea Fair Trade Commission (Article 69-3 of the Amended Act).

4. Scope of Applicability of the Amended Act

The effective date of the patent-market approval linkage system is set forth in the addendum of the Amended Act. The provisions related to the Patent Holder's request for a stay against the sale of generic drugs will apply from the case where a Patent Challenge Notice is delivered to an original drug company by a generic approval (or amendment approval) applicant after the enforcement of the

Amended Act (Article 2 of the Addendum of the Amended Act).

The provisions related to the first generic exclusivity will apply to the case where an application is made for market approval or amendment approval for a generic drug for which a notice must be given under the Amended Act after its enforcement date (Article 4 of the Addendum of the Amended Act). For your information, if a generic approval application has been made before the enforcement date of the Amended Act on the condition that it would not challenge the listed patent of the original drug company, and after the enforcement date of the Amended Act, an application for amendment approval challenging the listed patent is made with a Patent Challenge Notice, then the applicant may be eligible to apply for first generic exclusivity (Article 12 of the Amended Act).

5. Conclusion

Prior to the Amended Act, original drug companies could prevent the sale of generic drugs based on its patent only after obtaining a favorable court decision or judgment. Under the Amended Act, original drug companies may prevent the release of generic drugs without a court decision. As a result, patents on original drugs now have far stronger force than other types of patents, providing greater protection to original drug companies. On the other hand, the Amended Act grants a 9-month first generic exclusivity to generic drug companies that succeed in challenging patents of original drugs, which will encourage generic drug companies to actively challenge the listed patents. This will serve as a balancing mechanism to verify in advance whether the greater protection for a particular original drug under the patent-market approval linkage system is warranted. Considering that Korea has a drug pricing system where the price of an original drug automatically decreases when a new generic drug enters into the market, the introduction of the patent-market approval linkage system and first generic exclusivity will have a broad impact beyond the legal relations between private companies. Therefore, it would be critical to find reasonable and efficient ways to utilize the newly introduced system on a broader scale, taking into account the interests of consumers and public health care policies, as well as the financial soundness of the National Health Insurance Service.

Should you have any questions regarding any of the foregoing, please feel free to contact us at any time.

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